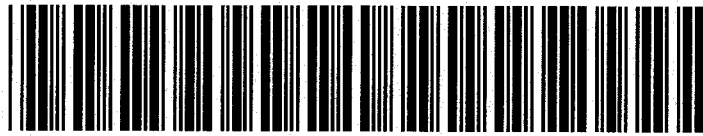


EXHIBIT B



**SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO**

Document Scanning Lead Sheet

Mar-28-2019 10:41 am

Case Number: CGC-19-574872

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COMPLAINT

CITY OF SANTA ANA ET AL VS. PURDUE PHARMA L.P

001C06744727

Instructions:

Please place this sheet on top of the document to be scanned.

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Roman Silberfeld, Bar No. 62783 Lucas A. Messenger, Bar No. 217645 ROBINS KAPLAN LLP 2049 Century Park East, Suite 3400 Los Angeles, CA 90067 TELEPHONE NO.: 310-552-0130 FAX NO.: 310-229-5800 ATTORNEY FOR (Name): Plaintiffs City of Santa Ana and People of the State of California		FOR COURT USE ONLY FILED San Francisco County Superior Court MAR 28 2019 CLERK OF THE COURT BY: <i>[Signature]</i> Deputy Clerk	
SUPERIOR COURT OF CALIFORNIA, COUNTY OF San Francisco STREET ADDRESS: 400 McAllister Street MAILING ADDRESS: 400 McAllister Street CITY AND ZIP CODE: San Francisco, CA 94102-4515 BRANCH NAME: Civic Center Courthouse			
CASE NAME: City of Santa Ana, et al. v. Purdue Pharma L.P., et al.			
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000)	<input type="checkbox"/> Limited (Amount demanded is \$25,000 or less)	Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)	CASE NUMBER: CGC-19-574872 JUDGE: DEPT:

Items 1-6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input type="checkbox"/> Product liability (24) <input type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other PI/PD/WD (23) Non-PI/PD/WD (Other) Tort <input checked="" type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-PI/PD/WD tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Rule 3.740 collections (09) <input type="checkbox"/> Other collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/Inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403) <input type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)
---	--	---

2. This case ☒ is ☐ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- a. ☒ Large number of separately represented parties d. ☒ Large number of witnesses
- b. ☒ Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve e. ☒ Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
- c. ☒ Substantial amount of documentary evidence f. ☒ Substantial postjudgment judicial supervision
3. Remedies sought (check all that apply): a. ☒ monetary b. ☒ nonmonetary; declaratory or injunctive relief c. ☒ punitive

4. Number of causes of action (specify): nine

5. This case ☐ is ☒ is not a class action suit.

6. If there are any known related cases, file and serve a notice of related case. (You may use form CM-015.)

Date: March 27, 2019

Roman Silberfeld, Bar No. 62783

(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

CM-010

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you must complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check one box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the primary cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than \$25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort

Auto (22)—Personal Injury/Property Damage/Wrongful Death
Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort

Asbestos (04)
Asbestos Property Damage
Asbestos Personal Injury/
Wrongful Death
Product Liability *(not asbestos or toxic/environmental)* (24)
Medical Malpractice (45)
Medical Malpractice—
Physicians & Surgeons
Other Professional Health Care
Malpractice
Other PI/PD/WD (23)
Premises Liability (e.g., slip and fall)
Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
Intentional Infliction of Emotional Distress
Negligent Infliction of Emotional Distress
Other PI/PD/WD

Non-PI/PD/WD (Other) Tort

Business Tort/Unfair Business Practice (07)
Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
Defamation (e.g., slander, libel) (13)
Fraud (16)
Intellectual Property (19)
Professional Negligence (25)
Legal Malpractice
Other Professional Malpractice *(not medical or legal)*
Other Non-PI/PD/WD Tort (35)
Employment
Wrongful Termination (36)
Other Employment (15)

Contract

Breach of Contract/Warranty (06)
Breach of Rental/Lease
Contract *(not unlawful detainer or wrongful eviction)*
Contract/Warranty Breach—Seller Plaintiff *(not fraud or negligence)*
Negligent Breach of Contract/
Warranty
Other Breach of Contract/Warranty
Collections (e.g., money owed, open book accounts) (09)
Collection Case—Seller Plaintiff
Other Promissory Note/Collections Case
Insurance Coverage *(not provisionally complex)* (18)
Auto Subrogation
Other Coverage
Other Contract (37)
Contractual Fraud
Other Contract Dispute

Real Property

Eminent Domain/Inverse
Condemnation (14)
Wrongful Eviction (33)
Other Real Property (e.g., quiet title) (26)
Writ of Possession of Real Property
Mortgage Foreclosure
Quiet Title
Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer

Commercial (31)
Residential (32)
Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review

Asset Forfeiture (05)
Petition Re: Arbitration Award (11)
Writ of Mandate (02)
Writ—Administrative Mandamus
Writ—Mandamus on Limited Court Case Matter
Writ—Other Limited Court Case Review
Other Judicial Review (39)
Review of Health Officer Order
Notice of Appeal—Labor
Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)

Antitrust/Trade Regulation (03)
Construction Defect (10)
Claims Involving Mass Tort (40)
Securities Litigation (28)
Environmental/Toxic Tort (30)
Insurance Coverage Claims
(arising from provisionally complex case type listed above) (41)

Enforcement of Judgment

Enforcement of Judgment (20)
Abstract of Judgment *(Out of County)*
Confession of Judgment *(non-domestic relations)*
Sister State Judgment
Administrative Agency Award *(not unpaid taxes)*
Petition/Certification of Entry of Judgment on Unpaid Taxes
Other Enforcement of Judgment Case

Miscellaneous Civil Complaint

RICO (27)
Other Complaint *(not specified above)* (42)
Declaratory Relief Only
Injunctive Relief Only *(non-harassment)*
Mechanics Lien
Other Commercial Complaint Case *(non-tort/non-complex)*
Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition

Partnership and Corporate Governance (21)
Other Petition *(not specified above)* (43)
Civil Harassment
Workplace Violence
Elder/Dependent Adult Abuse
Election Contest
Petition for Name Change
Petition for Relief from Late Claim
Other Civil Petition

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF SANTA ANA; and
(LO ESTÁ DEMANDANDO EL DEMANDANTE): THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Santa Ana City Attorney Sonia R. Carvalho

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es):

San Francisco County Superior Court
Civic Center Courthouse
400 McAllister Street
San Francisco, CA 94102-4515

CASE NUMBER:
(Número del Caso):

CGC-19-574872

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800

Lucas A. Messenger, Bar No. 217645

ROBINS KAPLAN LLP

Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

CLERK OF THE COURT

Clerk, by

(Secretario)

Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):
3. ☐ on behalf of (specify):

under: ☐ CCP 416.10 (corporation)

☐ CCP 416.20 (defunct corporation)

☐ CCP 416.40 (association or partnership)

☐ other (specify):

4. ☐ by personal delivery on (date):

☐ CCP 416.60 (minor)

☐ CCP 416.70 (conservatee)

☐ CCP 416.90 (authorized person)

(SEAL)



SUM-200(A)

SHORT TITLE: City of Santa, et al. v. Purdue Pharma
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
→ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
THE PURDUE FREDERICK COMPANY;
RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER FAMILY;
JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER FAMILY;
MORTIMER D.A. SACKLER, an individual;
KATHE A. SACKLER, an individual;
IRENE SACKLER LEFCOURT, an individual;
BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
DAVID A. SACKLER, an individual;
CEPHALON, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
JANSSEN PHARMACEUTICALS, INC.;
JOHNSON & JOHNSON;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS INC.;
ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS PHARMA, INC.;
ACTAVIS LLC;
ALLERGAN PLC;
ALLERGAN, INC.;
ALLERGAN USA, INC.;
INSYS THERAPEUTICS, INC.;
MALLINCKRODT, PLC;
MALLINCKRODT, LLC;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
MCKESSON CORPORATION; and
DOES 1-100, inclusive,

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

ORIGINAL

FAXED

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Attorneys for Plaintiffs City of Santa Ana and The
People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

CITY OF SANTA ANA; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Santa Ana
City Attorney Sonia R. Carvalho,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

FILED
San Francisco County Superior Court

MAR 28 2019

CLERK OF THE COURT
By: *[Signature]*
Deputy Clerk

CGC - 19 - 574872

Case No.

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;
8. FRAUDULENT TRANSFER; and

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

1 SACKLER, an individual; IRENE
2 SACKLER LEFCOURT, an individual;
3 BEVERLY SACKLER, an individual and
4 as trustee for TRUST FOR THE BENEFIT
5 OF MEMBERS OF THE RAYMOND
6 SACKLER FAMILY; THERESA
7 SACKLER, an individual; DAVID A.
8 SACKLER, an individual; CEPHALON,
9 INC.; TEVA PHARMACEUTICAL
10 INDUSTRIES, LTD.; TEVA
11 PHARMACEUTICALS USA, INC.;
12 JANSSEN PHARMACEUTICALS, INC.;
13 JOHNSON & JOHNSON; ORTHO-
14 MCNEIL-JANSSEN
15 PHARMACEUTICALS, INC.; JANSSEN
16 PHARMACEUTICA, INC.; ENDO
17 HEALTH SOLUTIONS INC.; ENDO
18 PHARMACEUTICALS INC.; ACTAVIS
19 PLC; WATSON PHARMACEUTICALS,
20 INC.; WATSON LABORATORIES, INC.;
21 ACTAVIS PHARMA, INC.; ACTAVIS
22 LLC; ALLERGAN PLC; ALLERGAN,
23 INC.; ALLERGAN USA, INC.; INSYS
24 THERAPEUTICS, INC.;
25 MALLINCKRODT, PLC;
26 MALLINCKRODT, LLC; CARDINAL
27 HEALTH, INC.;
28 AMERISOURCEBERGEN
CORPORATION; MCKESSON
CORPORATION; and
DOES 1-100, inclusive,

Defendants.

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Santa Ana Through Illicit Channels.....	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Santa Ana Through Illicit Channels	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Santa Ana	72
I.	The Statutes of Limitations Are Tolerated and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

1 **I. INTRODUCTION**

2 1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff
3 City of Santa Ana (hereinafter, "Santa Ana") has been particularly hard hit, causing Santa Ana to
4 suffer substantial loss of resources, economic damages, and damages to the health and welfare of
5 its citizens.

6 2. Santa Ana, California, by and through its attorneys hereto and its City Attorney,
7 hereby brings this action on its own behalf for injuries suffered and on behalf of the People of Santa
8 Ana (the "People," and together with Santa Ana, "Plaintiff") to protect the public from false and
9 misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

10 3. Opioid analgesics are widely diverted and improperly used, and the widespread
11 abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The
12 opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain
13 medications."²

14 4. This epidemic has been building for years. The conditions for its creation and
15 acceleration were intentionally brought about by Defendants, who made billions of dollars off the
16 epidemic.

17 5. The effects of the opioid epidemic and resulting health care crisis have been
18 exacerbated by Defendants' efforts to conceal or minimize the risks of opioid abuse, while at the
19 same time circumventing or ignoring any safeguards against opioid abuse.

20 6. Santa Ana has seen increased costs of, among other things, (a) medical and
21 therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose,
22 or death; (b) counseling, treatment and rehabilitation services; (c) treatment of infants born with
23 opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer
24 from opioid-related disability or incapacitation, including costs of related legal proceedings; (e)
25 public safety connected to the opioid epidemic within Santa Ana, including police, emergency

26
27 ¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

28 ² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 response services, and detention centers; (f) increased burden on Santa Ana's code enforcement
2 programs; (g) re-education of doctors and patients about the appropriate use of opioids; and (h)
3 extensive clean-up of public parks, spaces, and facilities. At the same time, Santa Ana has seen a
4 reduction to tax revenues caused by the epidemic created by the Defendants. Almost every citizen
5 of Santa Ana has been affected. The resulting damage to Santa Ana was directly and foreseeably
6 caused by Defendants' actions.

7 7. These increased costs could have been—and should have been—prevented by the
8 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
9 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
10 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
11 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
12 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
13 protecting opioids from theft, misuse, and diversion.

14 8. Instead of acting with reasonable care and in compliance with their legal duties,
15 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
16 process.

17 9. At the same time, Defendants flooded the market with false statements designed to
18 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
19 claims were false.³

20 10. Defendants' actions have not only caused significant costs, but have also created a
21 palpable climate of fear, distress, dysfunction and chaos among Santa Ana residents where opioid
22 diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

23 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
24 and/or unlawful conduct.

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26
27
28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. Santa Ana, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. Santa Ana has standing to recover damage incurred because of Defendants' actions and omissions. Santa Ana has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and Janssen's profits inure to J&J's benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen").

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as "Endo").

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as "Actavis").

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

1 Allergan, Inc., and Allergan USA, Inc. are referred to as "Allergan"). Allergan manufactures,
2 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
3 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
4 California with the California Secretary of State.

5 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
6 principal place of business located in Chandler, Arizona.

7 38. Insys manufactures, promotes, sells, and distributes opioids. Insys' principal source
8 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
9 United States, including California. Subsys was indicated by the FDA for the treatment of
10 breakthrough cancer pain that other opioids could not eliminate.

11 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
12 bribe physicians with purported speaking fees for marketing and education events in exchange for
13 them prescribing Subsys for off-label uses. Insys' founder and several other former Insys executives
14 were recently indicted by federal prosecutors on racketeering charges, alleging that these
15 individuals approved and fostered fraudulent behavior against insurance companies and also
16 conspired to bribe practitioners in various states. Insys Group is registered to do business in
17 California with the California Secretary of State.

18 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
19 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
20 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
21 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
22 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt").

23 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
24 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
25 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
26 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
27 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
28 Products are registered to do business in California with the California Secretary of State.

1 42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and
2 Mallinckrodt are the "Manufacturer Defendants."

3 **C. The Distributor Defendants**

4 43. CARDINAL HEALTH, INC. ("Cardinal") is a publicly traded company
5 incorporated under the laws of Ohio and with a principal place of business in Ohio.

6 44. Cardinal distributes prescription opioids to providers and retailers, including in
7 California. Cardinal has engaged in consensual commercial dealings with Santa Ana and its
8 residents, and has purposefully availed itself of the advantages of conducting business with and
9 within Santa Ana. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health
10 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with
11 the California Secretary of State.

12 45. AMERISOURCEBERGEN CORPORATION ("AmerisourceBergen") is a publicly
13 traded company incorporated under the laws of Delaware and with a principal place of business in
14 Pennsylvania.

15 46. AmerisourceBergen distributes prescription opioids to providers and retailers,
16 including in California. AmerisourceBergen has engaged in consensual commercial dealings with
17 Santa Ana and its residents, and has purposefully availed itself of the advantages of conducting
18 business with and within Santa Ana. AmerisourceBergen is in the chain of distribution of
19 prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen
20 Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services
21 Corporation are registered to do business in California with the California Secretary of State.

22 47. MCKESSON CORPORATION ("McKesson") is a publicly traded company
23 incorporated under the laws of Delaware and with a principal place of business in San Francisco,
24 California.

25 48. McKesson distributes prescription opioids to providers and retailers, including in
26 California. McKesson has engaged in consensual commercial dealings with Santa Ana and its
27 residents, and has purposefully availed itself of the advantages of conducting business with and
28 within Santa Ana. McKesson is in the chain of distribution of prescription opioids. McKesson

1 Corporation is registered to do business in California with the California Secretary of State.

2 49. The data which reveals and/or confirms the identity of the other wrongful opioid
3 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
4 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
5 voluntarily disclose the data necessary to identify with specificity the transactions which will form
6 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

7 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
8 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
9 listed on the New York Stock Exchange and their principal business consists of the nationwide
10 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
11 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
12 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
13 suspicious orders. Santa Ana has reason to believe each has engaged in unlawful conduct which
14 resulted in the distribution, dispensing, and diversion of prescription opioids into Santa Ana. Santa
15 Ana names each of the "Big 3" herein as defendants and places the industry on notice that Santa
16 Ana is acting to abate the public nuisance plaguing its community. Distributor Defendants have
17 had substantial contacts and business relationships with the People of Santa Ana. Distributor
18 Defendants have purposefully availed themselves of business opportunities within Santa Ana.

19 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
20 Defendants."

21 **D. The Doe Defendants**

22 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
23 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
24 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
25 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
26 is informed and believes, and on such information and belief alleges, that each of the Defendants
27 named as a DOE is responsible in some manner for the events and occurrences alleged in this
28 Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

53. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance in Santa Ana, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

54. Venue is proper in this Court because Defendants transact business in California and San Francisco County, and some of the acts complained of occurred in this venue. Furthermore, Defendant Distributor McKesson's principal place of business is in San Francisco County, and McKesson conducted business and continues to do business throughout the United States and in the State of California by regularly and continuously distributing prescription opioids throughout the State of California.

IV. GENERAL FACTUAL ALLEGATIONS**A. An Overview of the Opioid Epidemic**

55. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death."⁵

56. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

57. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

1 director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have
2 very, very high inherent risks . . . and there's no such thing as a fully safe opioid."⁶

3 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
4 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
5 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

6 59. Before the 1990s, generally accepted standards of medical practice dictated that
7 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
8 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
9 patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as
10 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
11 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
12 generally did not prescribe opioids for chronic pain.

13 60. The market for chronic pain patients, however, was much larger, and to take
14 advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for
15 chronic pain.⁷

16 61. As described herein, Defendants engaged in conduct that directly caused doctors to
17 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
18 obligations to prevent diversion of the highly addictive substance.

19 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
20 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
21 for every person in the United States to have a bottle of pills. This represents an increase of 300%
22 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
23 were dispensed per 100 persons.

24 63. Many Americans, including Californians and residents of Santa Ana, are now
25

26 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
Integrity, available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
27 [unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

28 ⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times
(May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20,
2017).

1 addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United
 2 States, an increase of more than 22 percent over the previous year. The New York Times reported
 3 in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly
 4 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 5 a public health emergency by the President of the United States. The wave of opioid addiction was
 6 created by the increase in prescriptions.

7 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 8 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 9 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 10 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 11 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 12 80 percent of people who use heroin first misused prescription opioids.

13 65. Drug overdose deaths among all Americans increased more than 200 percent
 14 between 1999 and 2015.

15 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 16 there were 4,654 total opioid overdose deaths in 2016.⁹

17 ///

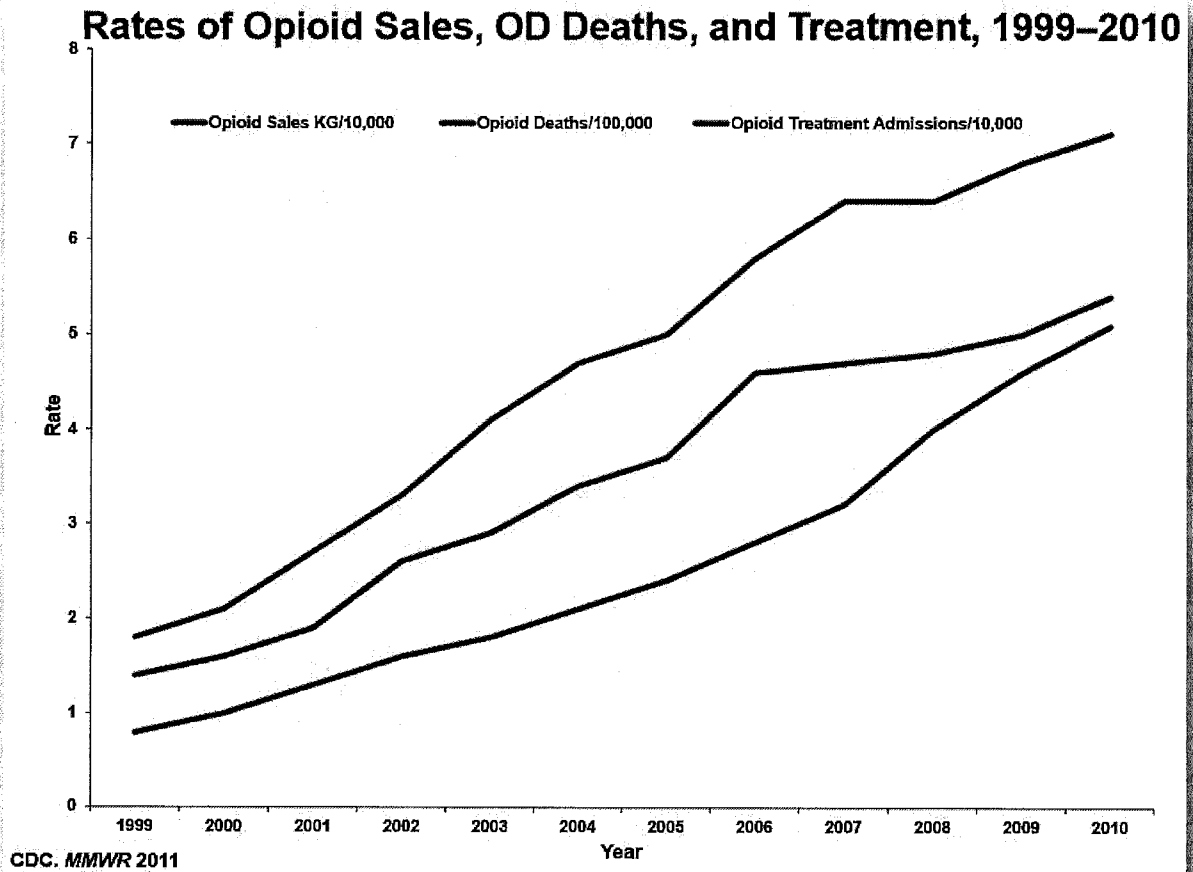
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26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*,” N.Y.
 27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, California Opioid Summary, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in Santa Ana, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants’ messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
2 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
3 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
4 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
5 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
6 carried a low, or no, risk of addiction.

7 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
8 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
9 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
10 of actual addiction began appearing, and advocated that the signs of addiction should be treated
11 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
12 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
13 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
14 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
15 opioid use, including the supposed ability of opioids to improve function and quality of life, even
16 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
17 claims.

18 75. These statements were not only unsupported by or contrary to the scientific
19 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
20 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
21 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

22 76. The Manufacturer Defendants began their marketing schemes decades ago and
23 continue them today.

24 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
25 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
26 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
27
28

1 annually since 2009.¹³ In an open letter to the nation's physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors.
 3 .. [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain."¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants' misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use "additional caution and
 21 increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
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27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, supra note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
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25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 27 29, 2017).

28 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient
 Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at [https://www.npr.org/sections/thetwo-
 way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-
 report-says](https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says) (last accessed February 23, 2018).

therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

100. The Manufacturer Defendants' deceptive, third-party, unbranded advertising often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising stated that "People who take opioids as prescribed usually do not become addicted." This directly contradicted its concurrent, branded advertising for Orpana ER, which warned that "use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

101. In addition to using third parties to disguise the source of their misinformation campaign, the Manufacturer Defendants also retained the services of a small group of physicians—known as "key opinion leaders" or "KOLs"—to convince both doctors and patients that opioid use to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the Manufacturer Defendants' KOLS were selected, funded, and elevated by the Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain.

102. Manufacturer Defendants paid these KOLs to serve as consultants or on their advisory boards and to give talks or present continuing medical education programs (CMEs), and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction, repaying Defendants by advancing their marketing goals. These KOLs' professional reputations became dependent on continuing to promote a pro-opioid message.

103. Pro-opioid doctors like the KOLs are one of the most important avenues that the Manufacturer Defendants use to spread their false and misleading statements about the risks and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for treatment of chronic pain through chronic opioid therapy without significant risk of addiction.

104. For example, the New York Attorney General ("NY AG") found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
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26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to

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27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

28 ¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in Santa Ana and doctors treating residents of Santa Ana.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
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26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at [http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_co](http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209)
[ntinued&view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209) (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 ²³ Dr. Portenoy was a member of the board of the APF.

28 ²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 119. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 120. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 121. On information and belief, AAPM is viewed internally by Endo as “industry

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26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 122. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

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27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in Santa Ana during the relevant time period, are still available online, and were often
 12 reprinted in the Journal of Pain, which is the official journal of the American Pain Society. The
 13 Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 126. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 128. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 129. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 130. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 131. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
25 marketing materials along with the rights to Kadian, it appears that Actavis
26 continued to use this brochure in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
28 People Living with Pain (2007), which suggests that addiction is rare and
limited to extreme cases of unauthorized dose escalations, obtaining
duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
61526107.2

- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."³¹
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Santa Ana, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants' misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 138. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain is *under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in Santa Ana, to PartnersAgainstPain.com, which contained false and
14 misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 Deceptive Claims of Pseudoaddiction

22 139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

29 140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
30 that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
31 pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
32 some of its proponents” and reported that despite the fact that Endo trained its sales representative
33 to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
34 Management testified to [the NY AG] that he was not aware of any research validating the
35 ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction
36

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 141. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including Santa Ana the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—“for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that available risk screening tools “show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

143. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

144. For example, on information and belief, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.³⁸ This publication was available on APF’s website until the organization dissolved in May 2012.

146. Detailers for Janssen have told and continue to tell doctors in California, including Santa Ana, that their patients would not experience withdrawal if they stopped using opioids.

Deceptive Minimization of Opioid Withdrawal

147. The Manufacturer Defendants also deceptively minimized the significant symptoms of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly understated the difficulty of tapering, particularly after long-term opioid use.

148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

1 recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]”
 2 to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,”
 3 because “physical dependence on opioids is an expected physiologic response in patients exposed
 4 to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that
 5 “more than a few days of exposure to opioids significantly increases hazards” and “each day of
 6 unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The
 7 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years
 8 on high dosages because of physical and psychological dependence” and highlights the difficulties,
 9 including the need to carefully identify “a taper slow enough to minimize symptoms and signs of
 10 opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The
 11 CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of
 12 different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

13 **Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk**

14 149. The Manufacturer Defendants also falsely claimed that doctors and patients could
 15 increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to
 16 patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer
 17 Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this
 18 misrepresentation, doctors would have abandoned treatment when patients built up tolerance and
 19 lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that
 20 were made by, and are continuing to be made by Defendants, are described below:

- 21 a. On information and belief, Actavis’s predecessor created a patient brochure for
 22 Kadian in 2007 that stated, “Over time, your body may become tolerant of
 23 your current dose. You may require a dose adjustment to get the right amount
 24 of pain relief. This is not addiction.” Upon information and belief, based on
 25 Actavis’ acquisition of its predecessor’s marketing materials along with the
 26 rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for*
 28 *People Living with Pain* (2007), which claims that some patients “need” a
 larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in Santa Ana that they should increase the dose of OxyContin, rather
than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir. Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was *no* evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in Santa Ana, that Opana ER is harder to abuse and given demonstrations to nurse
22 practitioners about Opana ER’s purported abuse deterrent properties.

24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-
push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou
ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those statements to be false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

158. Because Orpana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.

159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse, and that its abuse deterrent properties can be defeated.

160. These statements and omissions by Purdue are false and misleading, and conflict with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 430.

27 ⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose*
 28 *epidemic*, Business Insider (Mar. 14, 2016), available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

1 claiming that opioids allowed a patient to “continue to function.” This video is
2 still available today on YouTube.

- 3 i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s*
4 *Guide to Understanding Pain & Its Management*, which claimed that “multiple
5 clinical studies” have shown that opioids are effective in improving daily
6 function, psychological health, and health-related quality of life for chronic
7 pain patients.” The Policymaker’s Guide was originally published in 2011 is
8 still available online today.
- 9 j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER,
10 Purdue’s Vice President of Health Policy, J. David Haddox, talked about the
11 importance of opioids, including Purdue’s opioids, to chronic pain patients’
12 “quality of life,” and complained that CDC statistics do not take into account
13 that patients could be driven to suicide without pain relief.
- 14 k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed
15 and continue to convey to prescribers in California, including in Santa Ana, the
16 message that opioids will improve patient function.

17 171. The above claims find no support in the scientific literature. The FDA and other
18 federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved
19 by the FDA concluded that “there is *no good evidence* that opioids improve pain or function with
20 long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced
21 this conclusion throughout its 2016 Guideline, finding:

- 22 a. “No evidence shows a long-term benefit of opioids in pain and function versus
23 no opioids for chronic pain with outcomes examined at least 1 year later”
- 24 b. “Although opioids can reduce pain during short-term use, the clinical evidence
25 review found insufficient evidence to determine whether pain relief is
26 sustained and whether function or quality of life improves with long-term
27 opioid therapy.”
- 28 c. “[E]vidence is limited or insufficient for improved pain or function with long-
term use of opioids for several chronic pain conditions for which opioids are
commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and
inability to fulfill major role obligations.” As a matter of common sense (and medical evidence),
drugs that can kill patients or commit them to a life of addiction or recovery do not improve their
function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

1 173. The 2016 CDC Guideline was not the first time a federal agency repudiated the
2 Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the
3 FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical
4 experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating
5 pain, taken together with any drug-related side effects patients may experience ... results in any
6 overall positive impact on a patient's work, physical and mental functioning, daily activities, or
7 enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making
8 it publicly clear "that [the claim that] patients who are treated with the drug experience an
9 improvement in their overall function, social function, and ability to perform daily activities . . .
10 has not been demonstrated by substantial evidence or substantial clinical experience."

11 174. The Manufacturer Defendants also falsely and misleadingly emphasized or
12 exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look
13 to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants
14 frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of
15 analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer
16 Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from
17 opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and
18 have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious
19 risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene
20 pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed,
21 the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids
22 should only be used as a last resort "in patients for which alternative treatment options" like non-
23 opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

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25 ⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe,
26 CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at [http://wayback.archive-
it.org/7993/20170112063027/http://www.fda.gov/Drugs/
GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofVi
olationLetterstoPharmaceuticalCompanies/ucm259240.htm](http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm) (last accessed December 20, 2017).

27 ⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing
28 massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at
http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

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27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by Santa Ana.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

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27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

28 ⁵² *Id.*

1 misrepresentations deceived and continue to deceive doctors and patients in California, including
 2 in Santa Ana, about the risks and benefits of long-term opioid use. California doctors confirm this.
 3 Studies also reveal that many doctors and patients are not aware of or do not understand these risks
 4 and benefits. Indeed, patients often report that they were not warned they might become addicted
 5 to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid
 6 patients found that 4 out of 10 were not told opioids were potentially addictive. Plaintiff is informed
 7 and believes that California residents were never told that they might become addicted to opioids
 8 when they started taking them, were told that they could easily stop using opioids, or were told that
 9 the opioids they were prescribed were less addictive than other opioids.

10 192. Numerous doctors and substance abuse counselors in California note that many of
 11 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
 12 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
 13 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
 14 for opioid addiction.

15 193. The Manufacturer Defendants knew and should have known that their
 16 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
 17 when they made them.

18 194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
 19 properties of their opioids caused and continue to cause doctors in California, including doctors in
 20 Santa Ana, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis,
 21 and fibromyalgia, rather than prescribing less addictive medications. Absent Manufacturers
 22 Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids
 23 to as many patients, and there would not have been as many opioids available for misuse and abuse
 24 or as much demand for those opioids.

25 195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
 26 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
 27 California, including in Santa Ana. Opioids are the most common means of treatment for chronic
 28 pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per

1 year are prescribed a long-acting opioid.

2 196. In California, including Santa Ana, Manufacturer Defendants' deceptive marketing
3 of the abuse-deterrent properties of their opioids during the past few years has been particularly
4 effective. For example, one survey reports that pain specialists were more likely to recognize that
5 OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those
6 properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using
7 more of it than those who did not know it was an AD opioid. Although sales of AD opioids still
8 represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they
9 represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in
10 opioid sales revenue in 2015).

11 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 198. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 199. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 200. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 201. Diversion can occur at any point in the opioid supply chain.

4 202. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 "red flags" surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 205. Opioid diversion occurs at an alarming rate in the United States.

23 206. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 210. In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 211. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 212. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for Santa Ana and the people therein.

25 213. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

1 214. Thus, all opioid distributors are required to maintain effective controls against
2 opioid diversion. They are required to create and use a system to identify and report to the California
3 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
4 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
5 and/or orders of unusual frequency. To comply with these requirements, distributors must know
6 their customers, must conduct due diligence, must report suspicious orders, and must terminate
7 orders if there are indications of diversion.

8 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
9 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
10 their obligations under the CSA.

11 216. Under the CSA, anyone authorized to handle controlled substances must track
12 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
13 automated drug reporting system that records and monitors the flow of Schedule II controlled
14 substances from the point of manufacture through distribution to the point of sale. ARCOS
15 accumulates data on distributors' controlled substances and transactions, which are then used to
16 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
17 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
18 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
19 and current record of each substance manufactured, imported, received, sold, delivered, exported,
20 or otherwise disposed of.

21 217. Plaintiff does not bring causes of action based on violations of federal statutes and
22 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
23 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
24 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
25 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
26 prescription opioids.

1 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
2 **Opioids to Santa Ana Through Illicit Channels**

3 218. The Distributor Defendants have been and continue to be well-aware of problems
4 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance
5 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
6 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
7 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
8 that the DEA also provides distributors with data on controlled substance distribution patterns and
9 trends, including data on the volume and frequency of orders and the percentage of controlled
10 versus non-controlled purchases. The distributors are also given case studies, legal findings against
11 other registrants, and ARCOS profiles of their customers whose previous purchases may have
12 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
13 Defendants should look for in order to identify potential diversion.

14 219. Since 2007, the DEA has hosted at least five conferences to provide registrants with
15 updated information about diversion trends and regulatory changes that affect the drug supply
16 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
17 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
18 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
19 also request clarification on DEA policies, procedures, and interpretations of the CSA and
20 implementing regulations.

21 220. Since 2008, the DEA also has participated in numerous meetings and events with
22 the legacy Healthcare Distribution Management Association (HDMA), now known as the
23 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
24 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
25 guidance to the association concerning suspicious order monitoring, and the association has
26 published guidance documents for its members on suspicious order monitoring, reporting
27 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
28 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 Santa Ana and its residents. Each Distributor Defendant knew or should have known that the
7 opioids reaching Santa Ana were not being consumed for medical purposes and that the amount of
8 opioids flowing to Santa Ana was far in excess of what could be consumed for medically necessary
9 purposes.

10 232. The Distributor Defendants negligently or intentionally failed to adequately control
11 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
12 substances would have anticipated the danger of opioid diversion and protected against it by, for
13 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
14 greater oversight, security, and control of supply channels; (c) looking more closely at the
15 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
16 amounts greater than the populations in those areas would warrant; (d) investigating demographic
17 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
18 Santa Ana; (e) providing information to pharmacies and retailers about opioid diversion; and (f) in
19 general, simply following applicable statutes, regulations, professional standards, and guidance
20 from government agencies and using a little bit of common sense.

21 233. On information and belief, the Distributor Defendants made little to no effort to visit
22 the pharmacies servicing the areas around Santa Ana to perform due diligence inspections to ensure
23 that the controlled substances the Distributor Defendants had furnished were not being diverted to
24 illegal uses.

25 234. On information and belief, the compensation the Distributor Defendants provided
26 to certain of their employees was affected, in part, by the volume of their sales of opioids to
27 pharmacies and other facilities servicing the areas around Santa Ana, thus improperly creating
28 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid

1 abuse.

2 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
3 flooding the market in and around Santa Ana with highly addictive opioids would allow opioids to
4 fall into the hands of children, addicts, criminals, and other unintended users.

5 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
6 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
7 and death. It was also reasonably foreseeable that many of these injuries would be suffered by Santa
8 Ana residents, and that the costs of these injuries would be borne by Santa Ana.

9 237. The Distributor Defendants knew or should have known that the opioids being
10 diverted from their supply chains would contribute to the opioid epidemic faced by Santa Ana, and
11 would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
12 addiction, demand, illegal transactions, economic ruin, and human tragedy.

13 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
14 and around Santa Ana, but, on information and belief, they nevertheless persisted in a pattern of
15 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
16 with such frequency that they knew or should have known these commonly abused controlled
17 substances were not being prescribed and consumed for legitimate medical purposes.

18 239. The use of opioids by Santa Ana residents who were addicted or who did not have
19 a medically necessary purpose could not have occurred without the knowing cooperation,
20 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
21 Defendants adhered to effective controls to guard against diversion, Santa Ana and its residents
22 would have avoided significant injury.

23 240. The Distributor Defendants made substantial profits over the years based on the
24 diversion of opioids into Santa Ana. The Distributor Defendants knew that Santa Ana would be
25 unjustly forced to bear the costs of these injuries and damages.

26 241. The Distributor Defendants' intentional distribution of excessive amounts of
27 prescription opioids showed an intentional or reckless disregard for the safety of Santa Ana and its
28 residents. Their conduct poses a continuing threat to the health, safety, and welfare of Santa Ana.

1 242. The state laws at issue here are public safety laws.

2 243. The Distributor Defendants' violations constitute prima facie evidence of
3 negligence under state law.

4 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
5 **of Opioids to Santa Ana Through Illicit Channels**

6 244. The same legal duties to prevent diversion, and to monitor, report, and prevent
7 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
8 were also legally required of the Manufacturer Defendants under California law.

9 245. In addition to a common law duty to exercise reasonable care in the promotion and
10 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
11 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
12 determined by the Board. *See* 16 CCR 1782.

13 246. On information and belief, for over a decade the Manufacturer Defendants have
14 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
15 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
16 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
17 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
18 Manufacturer Defendants breached their duties under state law.

19 247. The Manufacturer Defendants had access to and possession of the information
20 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
21 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
22 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
23 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
24 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
25 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
26 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
27 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer
28 Defendants built receipt of this information into the payment structure for the opioids provided to

1 the opioid distributors.

2 248. The Manufacturer Defendants' actions and omission in failing to effectively prevent
3 diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful
4 diversion of opioids into Santa Ana.

5 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

6 249. As the demand for prescription opioids grew, fueled by their potency and purity,
7 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
8 traveling across state, city, and county lines in a variety of ways.

9 250. First, prescriptions written in one state would, under some circumstances, be filled
10 in a different state. But even more significantly, individuals transported opioids from one
11 jurisdiction specifically to sell them in another.

12 251. When authorities in one state cracked down on opioid suppliers, out-of-state
13 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
14 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
15 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
16 practice became so common that authorities dubbed these individuals "prescription tourists."

17 252. The facts surrounding numerous criminal prosecutions illustrate this common
18 practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught
19 flying to California in attempts to obtain additional sources of supply for their drug operation which
20 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

21 253. In another example, a man from Warren County, Ohio, who was sentenced to four
22 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
23 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
24 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a
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26 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

27 ⁵⁹ Andrew Welsh-Huggins, Associated Press, 'Prescription Tourists' Thwart States' Crackdown on Illegal
28 *Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

1 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
2 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
3 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
4 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
5 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
6 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

7 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
8 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
9 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
10 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
11 customers were from other states.⁶³

12 255. In yet another case, defendants who operated a pill mill in south Florida within
13 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
14 transported oxycodone back to the area for both use and distribution by local drug trafficking
15 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
16 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
17 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
18 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
19 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
20

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22 ⁶⁰ 16 Charged in ‘Pill Mill’ Pipeline, Columbus Dispatch (June 7, 2011), available at
<http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
23 accessed July 25, 2018).

24 ⁶¹ Associated Press, Leader of Ohio Pill-Mill Trafficking Scheme Sentenced, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
25 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

26 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead*
Guilty to Operating a “Pill Mill” in Lilburn, Georgia (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
27 accessed July 25, 2018).

28 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists*
Convicted for Illegally Dispensing to Patients of a Pill Mill (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
[patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

1 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
2 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
3 Kentucky residents.”⁶⁵

4 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
5 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
6 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
7 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
8 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
9 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
10 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
11 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
12 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

13 257. While the I-75 corridor was well utilized, prescription tourists also came from other
14 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
15 mills come from as far away as Arizona and Nebraska.⁷⁰

16 258. Similar pipelines developed in other regions of the country. For example, the I-95
17 corridor was another transport route for prescription pills. As the director of the Maine Drug
18 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
19 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
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21 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America's
Deadliest Drug Epidemic* 171 (2016).

24 ⁶⁷ *Id.* at 172

⁶⁸ *Id.* at 171

⁶⁹ *Id.*

25 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
26 *Sale of Painkillers*, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
(last accessed July 25, 2018).

27 ⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
28 (last accessed July 25, 2018)

1 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
2 Ohio, and Kentucky.

3 259. Along the west coast, over a million pills were transported from the Lake Medical
4 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²
5 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
6 Everett-based dealer who received the pills from southern California wore a diamond necklace in
7 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
8 OxyContin—connecting Los Angeles and Washington state.

9 260. Defendants certainly were aware, or should have been aware, that pill mills from
10 around the country were pushing its products. Defendants purchased nationwide, regional, state,
11 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
12 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
13 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
14 compute, and track their competitors' sales, and to compare and analyze market share information.

15 261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
16 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
17 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
18 regarding competing drugs, and analyzed the market share of those drugs.

19 262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
20 rewarded sales representatives who happened to have pill mills within their territories, enticing
21 those representatives to look the other way even when their in-person visits to such clinics should
22 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
23 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
24 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
25 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric

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27 ⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and
Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

28 ⁷³ *Id.*

1 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
2 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
3 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
4 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
5 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

6 ⁷⁴

7 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
8 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
9 sales representative "it was packed with a line out the door, with people who looked like gang
10 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
11 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
12 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
13 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
14 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
15 2010 to inform the authorities.

16 264. Abundant evidence, thus, establishes that prescription opioids migrated between
17 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
18 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
19 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
20 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
21 prescription opioid pills were hard to get in one area, they migrated from another. The
22 manufacturers and distributors were fully aware of this phenomenon and profited from it.

23 265. Defendants each knew or should have known that opioid diversion and abuse was
24 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide

25
26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

1 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
2 allowed to continue the unlawful diversion of opioids into Santa Ana.

3 **G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the**
4 **Harm Alleged Herein and Substantial Damages**

5 266. As the Manufacturer Defendants' efforts to expand the market for opioids increased,
6 so have the rates of prescription and the sale of their products, as well as the rates of opioid-related
7 substance abuse, hospitalization, and death among Santa Ana residents and across the nation.
8 Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of
9 opioids into communities like Santa Ana, fueling the epidemic.

10 267. There is a "parallel relationship between the availability of prescription opioid
11 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
12 associated adverse outcomes."⁷⁷

13 268. Opioids are widely diverted and improperly used, and the widespread use of the
14 drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

15 269. The epidemic is "directly related to the increasingly widespread misuse of powerful
16 opioid pain medications."⁷⁹

17 270. The increased abuse of prescription opioids—along with growing sales—has
18 contributed to a large number of overdoses and deaths.

19 271. As shown above, the opioid epidemic has escalated in Santa Ana with devastating
20 effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants'
21 increased distribution of opioids.

22 272. Because of the well-established relationship between the use of prescription opioids
23 and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to Santa
24 Ana and areas from which opioids are being diverted to Santa Ana, has caused the opioid epidemic
25 to include heroin addiction, abuse, and death.

26
27 ⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N.
Eng. J. Med. 241 (2015).

28 ⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

1 273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public
2 health and safety in Santa Ana.

3 274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and
4 safety in Santa Ana.

5 275. Defendants repeatedly and purposefully breached their duties under state law, and
6 such breaches are direct and proximate causes of, and/or substantial factors leading to, the
7 widespread diversion of prescription opioids for nonmedical purposes in Santa Ana.

8 276. The unlawful diversion of prescription opioids is a direct and proximate cause of,
9 and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction,
10 morbidity, and morality in Santa Ana. This diversion and the resulting epidemic are direct causes
11 of foreseeable harms incurred by Santa Ana and residents of Santa Ana.

12 277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past
13 and continuing, economic damages for which Santa Ana seeks relief, as alleged herein. Santa Ana
14 also seeks the means to abate the epidemic created by the Defendants.

15 278. Santa Ana seeks economic damages from the Defendants as reimbursement for the
16 costs associated with past efforts to eliminate the hazards to public health and safety.

17 279. Santa Ana seeks economic damages from the Defendants to pay for the costs to
18 permanently eliminate the hazards to public health and safety and abate the public nuisance.

19 280. Santa Ana seeks economic damages from the Defendants to pay for the reduction to
20 tax revenues caused by the epidemic created by the Defendants.

21 281. To eliminate the hazard to public health and safety, and abate the public nuisance, a
22 "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

23 282. A comprehensive response to this crisis must focus on preventing new cases of
24 opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective
25 opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

26 _____
⁸⁰ Rudd, *supra* note 51.

27 ⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An*
28 *Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at
<https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and->

1 283. The community-based problems require community-based solutions that have been
2 limited by budgetary constraints.

3 284. Having profited enormously through the aggressive sale, misleading promotion, and
4 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
5 financial burdens their conduct has inflicted upon Santa Ana.

6 285. The opioid epidemic still rages because the fines and suspensions imposed by the
7 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
8 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
9 registration numbers and when one facility is suspended, they simply ship from another facility.

10 286. The Defendants have abandoned their duties imposed by the law, taken advantage
11 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
12 Santa Ana.

13 287. In the course of conduct described in this Complaint, Defendants have acted with
14 oppression, fraud, and malice, both actual and presumed.

15 **H. The Impact of Opioid Abuse on Santa Ana**

16 288. Defendants' creation, through false and misleading advertising and a failure to
17 prevent diversion, of a virtually limitless opioid market has significantly harmed Santa Ana and
18 resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
19 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
20 abused come, directly or indirectly, through doctors' prescriptions.

21 289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
22 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
23 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
24 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
25 associated with the consumption of a counterfeit version of the prescription drug Norco
26 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has

27 _____
28 [effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf](https://www.cdph.ca/Programs/CID/DCDC/Pages/Effectiveness/Research/Prescription-Opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf) (last accessed
January 8, 2018).

1 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
 2 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
 3 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further
 4 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
 5 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
 6 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
 7 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
 8 related overdoses, with 55% of those resulting from prescription opioids.

9 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
 10 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
 11 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
 12 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
 13 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

14 291. Even Santa Ana's youngest residents bear the consequences of the opioid abuse
 15 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
 16 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
 17 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
 18 Many Santa Ana women have become addicted to prescription opioids and have used these drugs
 19 during their pregnancies. As a result, many Santa Ana infants suffer from opioid withdrawal and
 20 Neonatal Abstinence Syndrome ("NAS").⁸⁵

21
 22 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
year, LA Times (Oct. 27, 2014), available at [http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html)
[prescription-hospital-er-20141026-story.html](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html) (last accessed December 21, 2017).

23 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
 24 *The Opioid Crisis in Indian Country*, at 37, available at
<https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
 25 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US., 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

26 ⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
 27 Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
 28 21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at

1 292. The impact of NAS can be life-long. Most NAS infants are immediately transferred
2 to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require
3 an emergency evacuation for care to save the infant's life. Such emergency transportation can cost
4 thousands of dollars for each occurrence.

5 293. Many NAS infants have short-term and long-term developmental issues that prevent
6 them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and
7 digestive issues; some are unable to attend full days of school. These disabilities follow these
8 children through elementary school and beyond.

9 294. Many of the parents of these children continue to relapse into prescription opioid
10 use and abuse. As a result, many of these children are placed in foster care or adopted.

11 295. Opioid addiction is now the primary reason that Californians seek substance abuse
12 treatment, and admissions to drug treatment facilities in California more than doubled from
13 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one
14 facility in northern California, up to 90% – started on legal opioid prescriptions.

15 296. The explosion in opioid prescriptions and use caused by Defendants has led to a
16 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
17 overdoses and deaths as well as devastating social and economic consequences. This public health
18 crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable
19 enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]”
20 and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each
21 Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting
22 worse.

23 297. There is little doubt that each Defendant's deceptive marketing and distribution
24 scheme has precipitated this public health crisis in California, including Santa Ana, by dramatically
25 increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a
26 source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created
27

28 <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 a population of patients physically and psychologically dependent on them (the demand). And when
2 those patients can no longer afford or legitimately obtain opioids, they often turn to the street to
3 buy prescription opioids or even heroin.

4 298. The effects of Defendants' deceptive marketing and distribution scheme has further
5 impacted Plaintiff in a foreseeable way such that Santa Ana must devote increased resources to the
6 burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For
7 example, tax dollars are required to maintain public safety of places where the addicted homeless
8 attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight
9 the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
10 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
11 *aureus* (MRSA) are spread by opioid abuse.

12 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
13 have recruited addicts nationally with false and misleading promises of the medically supervised
14 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
15 effective rehabilitation available in beautiful California communities. These for-profit
16 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
17 that many have provided substandard care including use of physicians who have had their license
18 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
19 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
20 as long as there are third party payments available, and then throw them out of the facilities to be
21 homeless. These addicts brought to California by the substandard rehab industry, have further
22 contributed to the public's burden by discharging addicted homeless into the community who
23 require further care and rehabilitation at the public's expense, and who commit crimes in California
24 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
25 all relevant times when they deceptively marketed their products as non-addictive that such
26 addiction would be highly difficult to overcome. Defendants knew or should have known that
27 municipalities, including Santa Ana, would bear the burden of costs associated with rehabilitation
28 business of all types.

1 300. The role of Defendants' deceptive marketing and distribution scheme in causing this
 2 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
 3 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
 4 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have
 5 contributed to the severity of the current prescription drug abuse problem." And in August 2016,
 6 the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy
 7 marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids
 8 are not addictive when prescribed for legitimate pain." California doctors, addiction treatment
 9 specialists, and law enforcement and public health officials confirm that prescription opioids
 10 lawfully prescribed by doctors have fueled this epidemic.

11 301. Absent each Defendant's deceptive marketing scheme and improper distribution,
 12 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
 13 the opioid epidemic that now exists would have been averted or much less severe.

14 302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
 15 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
 16 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
 17 only engaged in false advertising, they have also created or assisted in the creation of a public
 18 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the
 19 present is part of its deceptive marketing and distribution scheme and subjects that Defendant to
 20 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
 21 *See* Cal. Civ. Code § 3490 ("No lapse of time can legalize a public nuisance, amounting to an actual
 22 obstruction of public right"); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 ("the maintenance
 23 of a public nuisance may not be defended on the ground of laches or the statute of limitations").

24 303. Accordingly, Defendants' conduct, both individually and collectively, has violated
 25 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
 26 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Santa Ana does not seek to limit the
 27 ability of doctors in California to prescribe opioids. Santa Ana does not ask this Court to weigh the
 28 risks and benefits of long-term opioid use. Instead, Santa Ana seeks an order requiring Defendants

1 to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations,
2 and to abate the public nuisance they have created. To redress and punish Defendants' previous and
3 current violations of law that cause and continue to cause harm to Santa Ana, Plaintiff seeks a
4 judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law.

5 304. By this action, Santa Ana further seeks to recoup tax dollars spent already for the
6 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
7 impact on this county and its communities, and to abate the opioid nuisance so Santa Ana will not
8 be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
9 wrongful conduct as alleged herein.

10 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
11 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
12 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
13 California spiked by 34% from 2011 to 2013.

14 306. Opioid abuse also contributes to a range of social problems including physical and
15 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
16 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
17 unemployment, and despair. More and more Santa Ana resources are needed to combat these
18 problems. The prescription opioid crisis also diminishes Santa Ana's available workforce,
19 decreases productivity, increases poverty, and requires greater governmental expenditures by Santa
20 Ana.

21 307. The prescription opioid crisis has directly financially injured Santa Ana. The crisis
22 has led to an increased demand for, *inter alia*, security services (such as police, EMS, detention),
23 child protective services, health services, clean-up services, and legal services. Santa Ana has also
24 had to hire additional staff and expend additional resources to manage the demand.

25 308. Santa Ana's medical services have seen an increase in opioid-related health
26 problems among Santa Ana residents, including, but not limited to, infants born with opioid-related
27 medical conditions. This has resulted in increased demand and increased expenses.

28 309. Santa Ana has also suffered substantial financial damages in the form of lost

1 productivity of Santa Ana employees and residents, lost economic activity, lost reputation and good
2 will, and the lost opportunity for growth. These damages have been suffered and continue to be
3 suffered directly by Santa Ana.

4 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
5 their homes and their families. Some will get treatment and fewer will successfully complete it;
6 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
7 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
8 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
9 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
10 drug transactions; or dying from opioid-induced heart or neurological disease.

11 311. Santa Ana also has suffered substantial financial damages in the form of lost taxes
12 paid by its residents and businesses as a result of lost earnings and productivity.

13 312. While the use of opioids has taken an enormous toll on Santa Ana and its residents,
14 Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in
15 revenue for drug companies like the Defendants. Indeed, on information and belief, each Defendant
16 experienced a material increase in sales, revenue, and profits from the unlawful conduct described
17 above.

18 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
19 **Asserting Statutes of Limitations As Defenses**

20 313. Defendants' conduct has continued from the early 1990s through today and remains
21 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
22 continuous injury. The damages have not occurred all at once but have continued to occur and have
23 increased as time progresses. The tort is not completed nor have all the damages been incurred until
24 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
25 public nuisance remains unabated.

26 314. Defendants are equitably estopped from relying upon a statute of limitations defense
27 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
28 assure the public that they were undertaking efforts to comply with their obligations under the

1 controlled substances laws, all with the goal of continuing to generate profits.

2 315. For example, a Cardinal Health executive claimed that it uses “advanced analytics”
3 to monitor its supply chain, and assured the public it was being “as effective and efficient as
4 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

5 316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
6 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
7 curbing the opioid epidemic in our country.”⁸⁷

8 317. Defendants, through their trade associations, filed an amicus brief that represented
9 that Defendants took their duties seriously, complied with their statutory and regulatory
10 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

11 318. Defendants purposely concealed their wrongful conduct, including by assuring the
12 public and governmental authorities that they were complying with their obligations and were
13 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
14 behavior by providing the public with false information about opioids and have continued to use
15 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
16 is continuing to this day.

17 319. Defendants have also concealed and prevented discovery of information, including
18 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
19 and illegal activities.

20 320. Defendants also lobbied Congress and actively attempted to halt DEA investigations
21

22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
24 https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html (last accessed December 21, 2017)

25 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
26 *Opioid Abuse,* Wash. Post, (Dec. 22, 2016), available at
27 https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed December 21,
28 2017).

⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4, 2016).

1 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
2 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a
3 distributor's license was raised.

4 321. In addition, the Defendants fraudulently attempted to convince the public that they
5 were complying with their legal obligations and working to curb the opioid epidemic.

6 322. Because the Defendants concealed the facts surrounding the opioid epidemic, Santa
7 Ana did not know if the existence or scope of the Defendants' misconduct, and could not have
8 acquired such knowledge earlier through the exercise of reasonable diligence.

9 323. Defendants intended that their false statements and omissions be relied upon,
10 including by Santa Ana, and its residents.

11 324. Defendants knew of their wrongful acts and had material information pertinent to
12 their discovery, but concealed that information from the public, including Santa Ana, and its
13 residents. Only Defendants knew of their widespread misinformation campaign and of their
14 repeated, intentional failures to prevent opioid diversion.

15 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
16 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
17 opioid crisis have only recently come to light.

18 326. Defendants had actual knowledge that their conduct was deceptive, and they
19 intended it to be deceptive.

20 327. Santa Ana was unable to obtain vital information regarding these claims absent any
21 fault or lack of diligence on Santa Ana's part.

22 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

23 **A. The Marketing Scheme**

24 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
25 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
26 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
27

28 ⁸⁹ See Higham and Bernstein, *supra* note 53.

1 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
2 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
3 long-term, chronic pain. Through their personal relationships, the members of this marketing
4 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
5 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
6 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

7 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
8 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
9 made misleading statements and misrepresentations about opioids that downplayed the risk of
10 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
11 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
12 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
13 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
14 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
15 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
16 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
17 formulations provide a solution to opioid abuse.

18 330. The marketing scheme devised, implemented and conducted by the Manufacturer
19 Defendants was designed to ensure that they unlawfully increased their sales and profits through
20 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
21 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
22 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
23 network as described above.

24 331. There was regular communication between the Manufacturer Defendants, Front
25 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
26 exchanged. Typically, the coordination, communication and payment occurred, and continues to
27 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
28 Defendants, Front Groups, and KOLs share information regarding overcoming objections and

1 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
2 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
3 each agreed and took actions to hide the scheme and continue its existence.

4 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'
5 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
6 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
7 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
8 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
9 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
10 their members and constituents. By failing to disclose this information, Front Groups perpetuated
11 the marketing scheme, and reaped substantial benefits.

12 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
13 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
14 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
15 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
16 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
17 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
18 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
19 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
20 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
21 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
22 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
23 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

24 334. As public scrutiny and media coverage focused on how opioids ravaged
25 communities in California and throughout the United States, the Front Groups and KOLs did not
26 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
27 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
28 using opioids for chronic pain.

1 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
2 categories of activities in furtherance of the marketing scheme. As described herein, the
3 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
4 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
5 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
6 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
7 and (d) efforts to limit prescriber accountability.

8 336. In addition to disseminating misrepresentations about the risks and benefits of
9 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
10 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
11 criticized or undermined the CDC Guidelines which represented "an important step – and perhaps
12 the first major step from the federal government - toward limiting opioid prescriptions for chronic
13 pain."

14 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
15 the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not
16 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
17 of the individuals who participated in the construction of these guidelines."

18 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
19 president, stating "that the CDC guideline makes disproportionately strong recommendations based
20 upon a narrowly selected portion of the available clinical evidence."

21 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
22 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
23 "neutral" and more "scientific" than the Manufacturer Defendants themselves. Without the work
24 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
25 scheme could not have achieved its common purpose.

26 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to
27 be prescribed and used for chronic pain throughout Santa Ana, and the epidemic continues to injure
28 Plaintiff, and consume the resources of Plaintiff's emergency health services and law enforcement

1 systems.

2 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
3 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
4 in the object of the scheme, and functioned within a structure designed to effectuate the scheme's
5 purpose.

6 **B. The Distribution Scheme**

7 342. Faced with the reality that they will now be held accountable for the consequences
8 of the opioid epidemic they created, members of the industry resort to "a categorical denial of any
9 criminal behavior or intent."⁹⁰ Defendants' actions went far beyond what could be considered
10 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
11 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
12 competitive, with the common purpose and achievement of vastly increasing their respective profits
13 and revenues by exponentially expanding a market that the law intended to restrict.

14 343. Knowing that dangerous drugs have a limited place in our society, and that their
15 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
16 and addiction causes to individuals, society and governments, California enacted California
17 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
18 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
19 to detect and report such activity.

20 344. If morality and the law did not suffice, competition dictates that the Distributor
21 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
22 if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior
23 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
24 dictates that it would do so.

25 345. The Distributor Defendants' scheme required the participation of all. If any one
26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

1 member broke rank, its compliance activities would highlight deficiencies of the others, and the
2 artificially high quotas they maintained through their scheme would crumble. But, if all the
3 members of the enterprise conducted themselves in the same manner, it would be difficult for state
4 authorities or the DEA to go after any one of them. Accordingly, through the connections they
5 made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the
6 Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly,
7 in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting
8 Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the
9 Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance
10 Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the
11 subsequent industry-wide enforcement actions and consent orders issued after that time, none of
12 them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult
13 to find the right balance between proactive anti-diversion efforts while not inadvertently limiting
14 access to appropriately prescribed and dispensed medications.” Yet, the Distributor Defendants
15 apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure
16 the largest possible financial return.

17 346. As described above, at all relevant times, the Distributor Defendants conspired
18 together for the purpose of unlawfully increasing sales, revenues and profits. In support of this
19 common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard
20 their statutory duties to identify, investigate, halt and report suspicious orders of opioids and
21 diversion of their drugs into the illicit market so that those orders would not result in a decrease, or
22 prevent an increase in, the necessary quotas.

23 347. At all relevant times, as described above, the Distributor Defendants exerted control
24 over, conducted and/or participated in distribution scheme by fraudulently claiming that they were
25 complying with their duties under California law to report suspicious orders and to maintain
26 systems to detect and report such activity.

27 348. While participating in their distribution scheme, Distributor Defendants applied
28 political pressure at the state and federal level to limit regulators’ ability to quickly and effectively

1 police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied
2 Congress to pass the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁹¹

3 349. The Distributor Defendants knowingly and intentionally furnished false or
4 fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material
5 information from reports, records and other document required to be filed with the California Board
6 of Pharmacy and the DEA including the Manufacturer Defendants’ applications for production
7 quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription
8 opioids and the diversion of their prescription opioids into the illicit market, and failed to report
9 this information to the California Board of Pharmacy and the DEA in their mandatory reports.

10 VI. MISCELLANEOUS FACTUAL ALLEGATIONS

11 350. FDA approval of opioids for certain uses did not give Defendants license to
12 misrepresent the risks and benefits of opioids. Indeed, Defendants’ misrepresentations were directly
13 contrary to pronouncements by and guidance from the FDA based on the medical evidence and
14 their own labels.

15 351. Defendants’ causal role in the opioid epidemic was not broken by the involvement
16 of doctors. Defendants’ marketing efforts were ubiquitous and highly persuasive. Their deceptive
17 messages tainted virtually every source doctors could rely on for information and prevented them
18 from making informed treatment decisions. Defendants also were able to harness and hijack what
19 doctors wanted to believe – namely, that opioids represented a means of relieving their patients’
20 suffering and of practicing medicine more compassionately.

21 ⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at
22 <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>
23 (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement*
24 *While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21,
25 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA*
26 *Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21,
27 2017); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston
28 *Gazette-Mail* (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 352. Each Defendant's conduct and role in creating or assisting in the creation of the
2 public health crisis now plaguing California is directly relevant to the amount of the civil penalties
3 to be awarded under California Business & Professions Code §.

4 353. As a members of the boards of various Purdue entities, the Sacklers oversaw all
5 aspects of Purdue's marketing and promotion of opioid products. As board members who were
6 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
7 known, of Purdue's deceptive marketing tactics of opioid products.

8 354. The Sackler Defendants also were aware of specific examples of deceptive
9 marketing through receipt of call note reviews in their capacities as board members. On information
10 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
11 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
12 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

13 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
14 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
15 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
16 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

17 356. By 2006, prosecutors at the United States Department of Justice found damning
18 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
19 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
20 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
21 events and side effects than other pain medications.

22 357. As members of the family that owns Purdue, the Sackler Defendants personally
23 benefitted from the success of OxyContin. At various points, as directors, they approved the
24 distribution of funds from Purdue to shareholders, including themselves and their extended family.

25 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
26 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
27 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
28 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of

Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy the opioid related liabilities of the companies from which they were transferred.

359. Plaintiff is informed and believes that due to the billions of dollars in profits that have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly profited and received the benefits of that wrongdoing.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)

360. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 359 above as if set forth fully herein.

361. California Civil Code § 3479 provides that “anything which is injurious to health ... or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property ... is a nuisance.”

362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

363. California Civil Code § 3490 states that “no lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right.”

364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought by Santa Ana to abate the public nuisance created by the Defendants.

365. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Santa Ana in violation of California Civil Code §§ 3479 and 3480.

1 366. The public nuisance is substantial and unreasonable. Defendants' actions caused and
2 continue to cause the public health epidemic described above in Santa Ana, and that harm
3 outweighs any offsetting benefit.

4 367. Defendants knew and should have known that their promotion and distribution of
5 opioids was false and misleading and that their deceptive marketing scheme would create or assist
6 in the creation of the public nuisance—i.e., the opioid epidemic.

7 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
8 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
9 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
10 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
11 so widespread, and the opioid epidemic that now exists would have been averted or much less
12 severe.

13 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
14 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
15 can be abated.

16 370. Each Defendant is liable for public nuisance because its conduct at issue is
17 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
18 endangers the safety, health, morals, comfort, or repose of a considerable number of people in Santa
19 Ana. Defendants' conduct is also indecent or offensive to the senses, and constitutes an obstruction
20 to the free use of property sufficient to constitute an interference with the people of Santa Ana's
21 comfortable enjoyment of life or property.

22 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
23 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
24 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
25 unreasonable interference with Santa Ana and its residents' public rights, including, but not limited
26 to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free
27 from disturbance and reasonable apprehension of danger to person or property.

28 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably

1 interfered with Santa Ana and its residents' public rights by, *inter alia*, engaging in a promotion
 2 and marketing scheme that pushed the use of opioids for indications not federally approved, and by
 3 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
 4 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
 5 Defendants failed to comply with federal law.

6 373. Defendants have also unlawfully and intentionally distributed opioids or caused
 7 opioids to be distributed within and without Santa Ana absent effective controls against diversion.
 8 Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain
 9 effective controls against diversion include Defendants' failure to effectively monitor for
 10 suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

11 374. Defendant's unreasonable interference with Santa Ana residents' public rights
 12 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
 13 expenditures to combat and address these harms. These damages have been suffered and continue
 14 to be suffered directly by Santa Ana and its residents.

15 375. Defendants' actions have also created a palpable climate of fear, distress,
 16 dysfunction and chaos among residents of Santa Ana where opioid diversion, abuse, and addiction
 17 are prevalent and where diverted opioids are used frequently. Specifically, Defendants conduct has
 18 caused, among other things, (a) routine separation of children from their parents who have fallen
 19 victim to easy access to opioids and/or related crime; (b) children to have easy access and to become
 20 addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for
 21 loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces
 22 and property; (e) property crimes throughout Santa Ana; (f) employers to lose the value of
 23 productive and healthy employees; (g) increased public health and safety costs; (h) a reduction in
 24 potential property values within Santa Ana; and (i) a decrease in tax revenues for Santa Ana.

25 376. The impact of Defendants' conduct on Santa Ana is of a continuing nature.
 26 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

27 377. Defendants knew or should have known that their actions would lead to the national
 28 opioid epidemic and to the resulting injuries to the public rights of Santa Ana.

1 378. Santa Ana has sustained a special and peculiar injury because its damages include,
2 *inter alia*, health service expenditures, public safety expenditures, payment of opioid addiction
3 treatment, decreased tax revenues, and a reduction in potential property values, and other costs
4 related to opioid addiction treatment and overdose prevention.

5 379. The externalized risks associated with Defendants' nuisance-creating conduct as
6 described herein greatly exceed the internalized benefits.

7 380. Defendants' actions are a direct and proximate contributing cause of the opioid
8 epidemic and the injuries to the public rights of Santa Ana and its residents.

9 381. Defendants, individually and collectively, are at the very least, a substantial factor
10 in causing the national opioid epidemic and of the injuries to Santa Ana and its residents.

11 382. The injuries to the public rights of Santa Ana and its residents are indivisible
12 injuries.

13 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
14 if unabated, will continue to cause an unreasonable interference with public rights of Santa Ana
15 and its residents.

16 384. Defendants' conduct is ongoing and persistent, and Santa Ana seeks all damages
17 flowing from Defendants' conduct. Santa Ana seeks economic losses (direct, incidental, and/or
18 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
19 above. Santa Ana does not seek damages for the wrongful death, physical personal injury, or
20 emotional distress caused by Defendants' actions.

21 385. Pursuant to Code of Civil Procedure § 731, Santa Ana requests an order providing
22 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
23 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

24 **SECOND CAUSE OF ACTION**
25 **(Fraud – Against All Defendants)**

26 386. Plaintiff realleges and incorporates herein by reference each and every allegation in
27 paragraphs 1 through 385 above as if set forth fully herein.

28 387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set

1 forth herein

2 388. The Defendants made fraudulent misrepresentations and omissions of material fact.
3 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
4 were intended to induce reliance.

5 389. Those misrepresentations and omissions were known to be untrue by the
6 Defendants, or were recklessly made.

7 390. As alleged herein, the Manufacturer Defendants engaged in false representations
8 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
9 dangers of abuse, and the risks of addiction.

10 391. As alleged herein, Defendants made false statements and/or omissions regarding
11 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
12 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
13 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
14 opioids, within Santa Ana.

15 392. Defendants made those misrepresentations and omissions in an intentional effort to
16 deceive Santa Ana and its residents, despite the Defendants' knowledge of the dangers of such use
17 of prescription opioids.

18 393. In addition and independently, Defendants had a duty not to deceive Plaintiff
19 because Defendants had in their possession unique material knowledge that was unknown, and not
20 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

21 394. The Defendants continued making those misrepresentations, and failed to correct
22 those material omissions, despite repeated regulatory settlements and publications demonstrating
23 the false and misleading nature of the Defendants' omissions and/or claims.

24 395. While Defendants had a duty to disclose the above-referenced material facts, they
25 nevertheless concealed them. These false representations and concealed facts were material to the
26 conduct and actions at issue. Defendants made these false representations and concealed facts with
27 knowledge of the falsity of their representations and did so with the intent of misleading Santa Ana,
28 its residents, the public, and persons on whom these entities relied.

1 396. Defendants intended and had reason to expect under the operative circumstances
2 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
3 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
4 and that these entities would act or fail to act in reasonable reliance thereon.

5 397. Santa Ana, its residents, and others, did in fact rightfully, reasonably, and justifiably
6 rely on Defendants' representations and/or concealments, both directly and indirectly.

7 398. For instance, doctors, including those serving Santa Ana and its residents, relied on
8 the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
9 Patients, including residents of Santa Ana, relied on the Defendants' misrepresentations and
10 omissions in taking prescription opioids for chronic pain relief.

11 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
12 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
13 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
14 effective response to the opioid crisis.

15 400. Defendants' misconduct alleged in this case is ongoing and persistent.

16 401. Santa Ana has experienced an unprecedented opioid addiction and overdose
17 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
18 services, and lost productivity to Santa Ana's workforce.

19 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
20 result of Defendants' fraudulent conduct.

21 403. As a direct and foreseeable consequence of Defendants' fraud, Santa Ana has
22 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
23 opioid addiction treatment and its secondary consequences in excess of those Santa Ana would
24 have otherwise incurred.

25 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
26 fraudulent, entitling Santa Ana to punitive damages.

27 ///

28 ///

THIRD CAUSE OF ACTION
(Negligence – Against All Defendants)

405. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 404 above as if set forth fully herein.

406. To establish actionable negligence in California, Plaintiff must show a duty, a breach of that duty, and injury resulting proximately therefrom.

407. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

408. In addition, Defendants had a duty not to breach the standard of care established under California law, including 16 CCR § 1782 and California Business and Professions Code §§ 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject to abuse, and to develop and maintain systems to detect and report such activity.

409. Defendants voluntarily undertook a legal duty to prevent the diversion of prescription opioids by engaging in the distribution of prescription opioids and by making public promises to prevent the diversion of prescription opioids.

410. Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

411. Defendants knew of the highly addictive nature of prescription opioids and of the high likelihood of foreseeable harm to patients and communities, including Santa Ana, from prescription opioid diversion.

412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and in accordance with applicable standards of conduct in advertising, marketing, selling, and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and municipal government such as Santa Ana which must incur enormous expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the

1 need to address the consequences of a large number of residents that become addicted to opioids as
2 a result of Defendants' conduct.

3 413. As described throughout the Complaint, Defendants breached their duties to
4 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
5 monitor for, failing to report, and filling highly suspicious orders time and again.

6 414. As described throughout the Complaint, in language expressly incorporated herein,
7 Defendants misrepresented their compliance with their duties under the law and concealed their
8 noncompliance and shipments of suspicious orders of opioids to Santa Ana and destinations from
9 which they knew opioids were likely to be diverted into Santa Ana, in addition to other
10 misrepresentations alleged and incorporated herein.

11 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
12 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
13 purported benefits of long-term use of opioids for the treatment of chronic pain.

14 416. Manufacturer Defendants knew or should have known, that their affirmative
15 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
16 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
17 representatives, and internal documents, should have put them on notice that such harm was not
18 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
19 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
20 and the public.

21 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
22 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

23 418. Defendants' misconduct alleged in this case is ongoing and persistent.

24 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
25 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
26 great probability of causing substantial harm.

27 420. As is described throughout this Complaint, Defendants acted without even slight
28 diligence or scant care, and with indifference, and were negligent in a very high degree,

1 disregarding the rights and safety of other persons, and said actions have a great probability of
2 causing substantial harm.

3 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
4 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
5 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
6 minimize the risk of addiction in patients and resultant harm to those patients, their families and
7 their communities, and to taxpayers and municipal government such as Santa Ana, including, but
8 not limited to, the following:

- 9 a. Foreseeability of harm to Santa Ana: Defendants were aware or reasonably
10 should have been aware of the risk of addiction of a large number of patients in
11 places such as Santa Ana, and need for their care and treatment and in handling
12 other consequences of their addiction and that such costs would be borne by
13 local governments such as Santa Ana;
14
15 b. Degree of certainty Santa Ana suffered harm: Santa Ana has suffered enormous
16 harm and costs in addressing treatment of addicted patients, including but not
17 limited to expenditures for prevention, treatment, emergency response and law
18 enforcement costs and other foreseeable costs related to the need to address the
19 consequences of a large number of residents that become addicted to opioids as
20 a result of Defendants' conduct;
21
22 c. Closeness of connection between Santa Ana's harm: The explosion of opioid
23 addiction and the presence of opioid addicted patients in Santa Ana as a result
24 of Defendants' conduct has resulted in expenditures directly for prevention,
25 treatment, emergency response and law enforcement costs and other foreseeable
26 costs related to the need to address the consequences;
27
28

- 1 d. Moral blame attached to Defendants' conduct: Defendants' knew or should have
2 known that their wrongful conduct, actions and omissions would result in an
3 explosion of patients who would become addicted to opioids, and that a vast
4 opioid epidemic would result from the prescription of opioids to tens of millions
5 of patients nationwide, including within Santa Ana, and that the costs would be
6 borne by the state, county and municipal local governments, while Defendants
7 profited tens of billions of dollars collectively from the widespread use of
8 prescription opioid products;
9
10 e. Policy of preventing future harm: As a direct and foreseeable result of
11 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
12 to occur on a vast scale both nationally and locally in places such as Santa Ana
13 resulting in tremendous harm and cost to the patients, their families and the
14 communities in dealing with this epidemic and crisis, and there is a need to
15 ensure that the costs of such wrongful conduct is borne by Defendants so that
16 parties contemplating such or similar conduct in the future know they will be
17 held responsible for such harm;
18
19 f. Extent of burden to Defendants: There is no burden to Defendants in that state
20 and other law precludes them from engaging in the conduct alleged herein, and
21 there is no burden from precluding Defendants from profiting from their
22 wrongful conduct and operating within the confines of the law in advertising,
23 marketing, selling and distributing opioid products in a safe manner to minimize
24 the risk of addiction in patients and resultant harm to those patients, their
25 families and their communities, and to taxpayers and municipal government
26 such as Plaintiff Santa Ana; and
27
28

g. Consequences to the community of imposing a duty to exercise care with resulting liability for breach: Imposing a duty to not engage in Defendants' wrongful conduct of advertising, marketing, selling and distributing opioid products in an unsafe manner would minimize the risk of addiction in patients, and liability for a breach of this duty would benefit communities such as Santa Ana in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the country and the nation.

422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled substances laws cited above.

423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for security services, emergency, health, prosecution, corrections, and rehabilitation services, as well as the cost of opioid addiction treatment paid by Santa Ana.

424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

425. Defendants' breaches of their duty of care foreseeably and proximately caused damage to Santa Ana and its residents.

426. Manufacturer Defendants are guilty of negligence per se in that the Defendants violated applicable California laws, statutes, and regulations, in the manner in which they advertised, marketed, sold and distributed opioid products.

427. Distributor Defendants are guilty of negligence per se in that the Defendants violated California laws, statutes, and regulations designed to protect Plaintiff from the harms it has suffered, including, but not limited to, the following:

- a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110390;

- b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110395;
- c. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;
- d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;
- e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and
- f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Santa Ana. Santa Ana, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Santa Ana to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

430. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

431. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Santa Ana, including from opioids foreseeably and deliberately diverted within and into Santa Ana.

432. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

433. These expenditures include, but are not limited to, the provision of emergency medical services and treatment services to people who use opioids.

434. These expenditures have helped sustain Defendants' businesses.

435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

436. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

438. Defendants' misconduct alleged in this case is ongoing and persistent.

439. Defendants have unjustly retained benefits to the detriment of Santa Ana, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

1 440. Santa Ana is entitled to restitution and disgorgement from Defendants in an amount
2 to be determined at trial.

3 **FIFTH CAUSE OF ACTION**
4 **(Civil Conspiracy – Against All Defendants)**

5 441. Plaintiff realleges and incorporates herein by reference each and every allegation in
6 paragraphs 1 through 440 above as if set forth fully herein.

7 442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
8 and/or distribution of opioids into California and Santa Ana.

9 443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
10 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
11 and Santa Ana.

12 444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
13 report, and prevent suspicious orders of opioids.

14 445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
15 conspiracy by increasing the volume of opioid sales in the United States through creating a market
16 for non-medical use of opioids of epidemic proportions.

17 446. Many of the Manufacturing Defendants are members, participants, and/or sponsors
18 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
19 the HDA to give further assistance to the conspiracy.

20 447. The Manufacturing Defendants hid from the general public and suppressed and/or
21 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
22 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
23 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

24 448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
25 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
26 to commit acts of fraud.

27 449. Indeed, for the Defendants’ fraudulent scheme to work, each of the Defendants had
28 to agree to implement similar tactics.

1 450. By intentionally refusing to report and halt suspicious orders of their prescription
2 opioids, Defendants engaged in a fraudulent scheme.

3 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
4 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
5 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
6 and were actually being diverted into the market of non-medical use.

7 452. Defendants further unlawfully marketed opioids in California and Santa Ana in
8 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
9 dissemination of false and misleading information about the safety and efficacy of long-term opioid
10 use through, among other things: (a) the use of "Front Groups" that appeared to be independent of
11 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
12 continuing medical education ("CME") programs controlled and/or funded by the Defendants; (d)
13 hiring and deploying so-called "key opinion leaders" or "KOLs" who were paid by the Defendants
14 to promote their message; and (e) the "detailing" activities of the Defendants' sales forces, which
15 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
16 physicians lacking the expertise of pain care specialists.

17 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
18 unbiased, independent patient-advocacy and professional organizations in order to disseminate
19 patient education materials, a body of biased and unsupported scientific "literature," and "treatment
20 guidelines" that promoted the Defendants' false messages.

21 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
22 influence prescribers' habits by promoting the Defendants' false message through, among other
23 things, writing favorable journal articles and delivering supportive CMEs as if they were
24 independent medical professionals, thereby further obscuring the Defendants' role in the
25 conspiracy.

26 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
27 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
28 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of

1 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
2 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
3 were industry-friendly and would work together with the Defendants to advance the conspiracy.

4 456. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this
5 Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes.
6 Such allegations are specifically incorporated herein.

7 457. Defendants acted with a common understanding or design to commit unlawful acts,
8 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
9 proximately caused the injuries alleged herein.

10 458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
11 reasonable or lawful excuse.

12 459. Defendants conduct in furtherance of the conspiracy described herein was not mere
13 parallel conduct because each Defendant acted directly against their commercial interests in not
14 reporting the unlawful distribution practices of their competitors to the authorities, which they had
15 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
16 actual or tacit agreement between the Defendants that they would not report each other to the
17 authorities so they could all continue engaging in their unlawful conduct.

18 460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
19 thereof, caused the direct and foreseeable losses alleged herein.

20 461. Defendants' misconduct alleged in this case is ongoing and persistent.

21 462. As a result of Defendants' conspiracy, Santa Ana is entitled to compensatory
22 damages in an amount to be proved at trial.

23 463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
24 fraudulent, entitling Santa Ana to punitive damages.

25 **SIXTH CAUSE OF ACTION**

26 **(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

27 464. Plaintiff realleges and incorporates herein by reference each and every allegation in
28 paragraphs 1 through 463 above as if set forth fully herein.

1 465. California Business & Professions Code § 17500 makes it unlawful for a business
2 to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning
3 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
4 exercise of reasonable care should be known, to be untrue or misleading.”

5 466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
6 designed to disseminate false or misleading statements designed to promote the belief that opioid
7 drugs could safely be used in a non-addictive manner.

8 467. By way of example, Actavis’s predecessor created a patient brochure for Kadian in
9 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome
10 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

11 468. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back
12 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
13 claimed that it is “less likely if you have never had an addiction problem.”

14 469. Cephalon and Purdue sponsored research and publications that falsely and
15 deceptively stated opioids did not have “ceiling dose.”

16 470. Purdue created websites, available to the public that instructed patients to seek new
17 medical providers out if their current provider would not increase their dose.

18 471. Defendants’ false and deceptive advertising practices resulted in increased opioid
19 dosages being prescribed to Santa Ana’s residents, increasing the incidence of opioid addiction and
20 overdose in Santa Ana.

21 472. Distributor Defendants also repeatedly omitted material information and/or falsely
22 represented that they were effectively preventing diversion and were monitoring, reporting, and
23 preventing suspicious orders.

24 473. As alleged above, Defendants’ statements about the risks associated with opioid use
25 were not supported by or were contrary to the scientific evidence.

26 474. As alleged above, each Defendant’s conduct, separately and collectively, was likely
27 to deceive California payors who purchased or covered the purchase of opioids.

28 475. Santa Ana seeks restitution and injunctive relief under California Business &

1 Professions Code § 17535.

2 476. Santa Ana also seeks an order assessing a civil penalty of two thousand five hundred
3 dollars (\$2,500) against Defendants for each violation of California's False Advertising Law
4 pursuant to California Business & Professions Code § 17536.

5 **SEVENTH CAUSE OF ACTION**

6 **(Negligent Failure to Warn– Against Manufacturer Defendants)**

7 477. Plaintiff realleges and incorporates herein by reference each and every allegation in
8 paragraphs 1 through 476 above as if set forth fully herein.

9 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
10 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
11 adequately warning the medical profession about the risk of addiction from the use of opioid
12 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
13 cancel out, and render meaningless any written warnings given about the risk of addiction from the
14 use of opioid products.

15 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
16 to adequately warn the medical profession about the risk of addiction from the use of opioid
17 products, including by overpromoting and over-marketing opioid products in a manner so as to
18 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
19 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
20 products in situations and for patients who should not have been using those drugs or should have
21 used them only as a last resort before other means were used or other less addictive and dangerous
22 drugs were prescribed.

23 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
24 and overpromoting and over-marketing the use of prescription opioid products, there is now a
25 national opioid addiction epidemic, including in Santa Ana. The People of Santa Ana, as a further
26 direct and proximate consequence and result thereof, sustained injuries and damages including but
27 not limited to tax dollars spent and costs for treatment of opioid addicted patients, emergency
28 response costs, law and regulatory enforcement costs, opioid disposal programs, and measures for

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ATTORNEYS AT LAW
LOS ANGELES

1 prevention of further opioid abuse and addiction.

2 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
3 fraudulent, entitling Santa Ana to punitive damages.

4 **EIGHTH CAUSE OF ACTION**
5 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler**
6 **Defendants)**

7 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
8 paragraphs 1 through 481 above as if set forth fully herein.

9 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
10 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
11 possess a right to payment from Purdue.

12 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
13 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
14 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
15 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

16 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
17 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
18 including Plaintiff.

19 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
20 them pursuant to California Civil Code § 3439.04(a)(1).

21 **NINTH CAUSE OF ACTION**
22 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

23 487. Plaintiff realleges and incorporates herein by reference each and every allegation in
24 paragraphs 1 through 486 above as if set forth fully herein.

25 488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
26 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
27 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
28 of its judgment against Purdue entered in this action.

489. After the Sackler Defendants became aware in or about 1999 that Purdue faced

1 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
2 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping
3 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
4 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
5 Defendants and their extended family.

6 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
7 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
8 to commit acts of fraud.

9 491. Purdue and the Sackler Defendants acted with a common understanding or design
10 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
11 excuse, which directly and proximately caused the injuries alleged herein.

12 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
13 unlawfully, and without a reasonable or lawful excuse.

14 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
15 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
16 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
17 judgment entered in this action.

18 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
19 compensatory damages in an amount to be proved at trial.

20 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
21 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

22 PRAYER FOR RELIEF

23 WHEREFORE, Santa Ana and the People respectfully request judgment in their favor
24 granting the following relief:

- 25
26 a) Entering Judgment in favor of Santa Ana and the People in a final order against
27 each of the Defendants;
28

- b) An award of actual and consequential damages in an amount to be determined at trial;
- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an "abatement fund" for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff's judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents

1 from selling, transferring, conveying, assigning, or otherwise disposing of any of
2 the property transferred to them by Purdue;

- 3 q) An order that the judgment granted herein be declared a lien against the property
4 transferred to the Sackler Defendants by Purdue;
- 5 r) An award of punitive damages;
- 6 s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- 7 t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to
8 California Code of Civil Procedure § 1021.5;
- 9 u) Pre- and post-judgment interest as allowed by law; and
- 10 v) Any other relief deemed just, proper, and/or equitable.

11 **PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE**

12 Dated: March 27, 2019

13 **ROBINS KAPLAN LLP**

14 By: 

15 Roman Silberfeld
16 Bernice Conn
17 Michael A. Geibelson
18 Lucas A. Messenger

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ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

NOTICE TO PLAINTIFF

A Case Management Conference is set for:

DATE: AUG-28-2019

TIME: 10:30AM

**PLACE: Department 610
400 McAllister Street
San Francisco, CA 94102-3680**

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference. However, it would facilitate the issuance of a case management order **without an appearance** at the case management conference if the case management statement is filed, served and lodged in Department 610 twenty-five (25) days before the case management conference.

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state. **This case is eligible for electronic filing and service per Local Rule 2.11. For more information, please visit the Court's website at www.sfsuperiorcourt.org under Online Services.**

[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]

ALTERNATIVE DISPUTE RESOLUTION REQUIREMENTS

IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE SHOULD PARTICIPATE IN MEDIATION, ARBITRATION, NEUTRAL EVALUATION, AN EARLY SETTLEMENT CONFERENCE, OR OTHER APPROPRIATE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A TRIAL.

(SEE LOCAL RULE 4)

Plaintiff **must** serve a copy of the Alternative Dispute Resolution (ADR) Information Package on each defendant along with the complaint. (CRC 3.221.) The ADR package may be accessed at www.sfsuperiorcourt.org/divisions/civil/dispute-resolution or you may request a paper copy from the filing clerk. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the ADR Information Package prior to filing the Case Management Statement.

**Superior Court Alternative Dispute Resolution Administrator
400 McAllister Street, Room 103-A
San Francisco, CA 94102
(415) 551-3869**

See Local Rules 3.3, 6.0 C and 10 B re stipulation to judge pro tem.

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11 Attorneys for Defendant
MCKESSON CORPORATION

12 *Additional counsel listed on signature page*
13

14 SUPERIOR COURT OF THE STATE OF CALIFORNIA
15 FOR THE COUNTY OF SAN FRANCISCO

16 CITY OF SANTA ANA; and THE PEOPLE OF
17 THE STATE OF CALIFORNIA, by and through
Santa Ana City Attorney Sonia R. Carvalho,

18 Plaintiff,

19 v.
20

21 PURDUE PHARMA L.P.; PURDUE PHARMA
INC.; THE PURDUE FREDERICK COMPANY;
22 RICHARD S. SACKLER, an individual and as
trustee for TRUST FOR THE BENEFIT OF
23 MEMBERS OF THE RAYMOND SACKLER
FAMILY; JONATHAN D. SACKLER, an
24 individual and as trustee for TRUST FOR THE
BENEFIT OF MEMBERS OF THE RAYMOND
25 SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A. SACKLER,
26 an individual; IRENE SACKLER LEFCOURT, an
27 individual; BEVERLY SACKLER, an individual
28 and as trustee for TRUST FOR THE BENEFIT OF

Civil Case No.: CGC-19-574872

**JOINT STIPULATION AND REQUEST TO
EXTEND TIME FOR DISTRIBUTOR
DEFENDANTS TO RESPOND TO
COMPLAINT; [PROPOSED] ORDER**

MEMBERS OF THE RAYMOND SACKLER
FAMILY; THERESA SACKLER, an individual;
DAVID A. SACKLER, an individual;
CEPHALON, INC.; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA
PHARMACEUTICALS USA, INC.; JANSSEN
PHARMACEUTICALS, INC.; JOHNSON &
JOHNSON; ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC.; ENDO HEALTH
SOLUTIONS INC.; ENDO
PHARMACEUTICALS INC.; ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC.;
WATSON LABORATORIES, INC.; ACTAVIS
PHARMA, INC.; ACTAVIS LLC; ALLERGAN
PLC; ALLERGAN, PLC.; ALLERGAN, INC.;
ALLERGAN USA, INC.; INSYS
THERAPEUTICS, INC.; MALLINCKRODT,
PLC; MALLINCKRODT, LLC; CARDINAL
HEALTH, INC.; AMERISOURCEBERGEN
CORPORATION; MCKESSON CORPORATION;
and DOES 1 THROUGH 100, inclusive,

Defendants.

1 McKesson Corporation (“McKesson”), AmerisourceBergen Corporation (“ABC”),¹ and Cardinal
2 Health, Inc. (“Cardinal”) (together, “Distributor Defendants”), by and through the undersigned counsel,
3 hereby submit this Stipulation for Extension of Time or Answer or Otherwise Respond to the Complaint.
4 Counsel for McKesson has consulted with Plaintiff’s Counsel, and Plaintiff stipulates to this request and
5 the relief sought herein. In support of this Stipulation, Distributor Defendants state as follows:

- 6 1. On March 28, 2019, Plaintiff commenced this action by filing the Complaint in the
7 Superior Court of the State of California for the County of San Francisco.
- 8 2. McKesson was served with the Complaint on March 28, 2019.
- 9 3. Currently, McKesson must respond to the Complaint by April 29, 2019.
- 10 4. ABC was served with the Complaint on April 4, 2019.
- 11 5. Currently, ABC must respond to the Complaint by May 6, 2019.
- 12 6. Cardinal was served with the Complaint on April 9, 2019.
- 13 7. Currently, Cardinal must respond to the Complaint by May 9, 2019.
- 14 8. The parties stipulate to enlarge the time for Distributor Defendants to respond to the
15 Complaint until June 28, 2019, which is sixty (60) days after the earliest date by which a Distributor
16 Defendant must currently respond to the Complaint.

17 THEREFORE, the parties, by and through their respective undersigned counsel, hereby stipulate
18 and agree to the following, and respectfully request that the Court enter this stipulation as an order:

19 Distributor Defendants shall be granted an extension of time to respond to Plaintiff’s Complaint
20 until June 28, 2019.

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28 ¹ By filing this Joint Stipulation and Request to Extend Time, AmerisourceBergen Corporation does not
concede that it is a proper party to this action.

1 DATED: April 17, 2019

Robins Kaplan LLP

2 By: /s/ Roman Silberfeld
3 Roman Silberfeld
4 Bernice Conn
5 Lucas A. Messenger
6 Michael A. Geibelson
7 Attorneys for Plaintiff
8 CITY OF SANTA ANA

9 DATED: April 17, 2019

COVINGTON & BURLING, LLP

10 By: /s/ Nathan Shafroth
11 Nathan Shafroth
12 Attorneys for Defendant
13 MCKESSON CORPORATION

14 DATED: April 17, 2019

BAKER & HOSTETLER LLP

15 By: /s/ Teresa C. Chow
16 Teresa C. Chow
17 Attorneys for Defendant
18 CARDINAL HEALTH, INC.

19 DATED: April 17, 2019

REED SMITH LLP

20 By: /s/ Steven Boranian
21 Steven Boranian
22 Sarah Johansen
23 Adam Brownrout
24 Attorneys for Defendant
25 AMERISOURCEBERGEN CORPORATION
26
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28

[PROPOSED] ORDER

Pursuant to the foregoing stipulation of the parties, and for good cause shown, the Court hereby grants the parties' request for an extension of time for Distributor Defendants to respond to Plaintiff's Complaint to and including June 28, 2019.

IT IS SO ORDERED.

DATED: _____

Hon. _____

PROOF OF SERVICE***City of Santa Ana, et al. v. Purdue Pharma, L.P. et al.
San Francisco Superior Court, Case No. CGC-19-574872***

I, the undersigned, declare as follows:

I am a citizen of the United States, over the age of 18 years, and not a party to, or interested in the within entitled action. I am employee of Covington & Burling, LLP, and my business address is Salesforce Tower, 415 Mission Street, San Francisco, CA 94105.

On April 17, 2019, I served the following document(s) on all parties in this action:

- **JOINT STIPULATION AND REQUEST TO EXTEND TIME FOR DISTRIBUTOR DEFENDANTS TO RESPOND TO COMPLAINT; [PROPOSED] ORDER**

☒ **BY ELECTRONIC SERVICE VIA FILE & SERVE XPRESS:** LexisNexis File & Serve for service on all counsel of record by electronic service pursuant to the Order Authorizing Electronic Service and pursuant to California Code of Civil Procedure § 1010.6 and California Rules of Court 2060(c). The transmission was reported as complete without error.

Roman Silberfeld Bernice Conn Michael A. Geibelson Lucas A. Messenger Robins Kaplan, LLP 2049 Century Park East, Suite 3400 Los Angeles, CA 90067 Tel.: (310) 552-0130 Fax: (310) 229-5800 rsilberfeld@robinskaplan.com bconn@robinskaplan.com mgeibelson@robinskaplan.com lmessenger@robinskaplan	Attorneys for Plaintiffs, CITY OF SANTA ANA and THE PEOPLE OF THE STATE OF CALIFORNIA
Sonia R. Carvalho Office of the City Attorney for Santa Ana 18101 Von Karman Ave, Ste. 1000 Irvine, CA 92612 Tel: (949) 263-2603 Fax: (949) 260-0972 sonia.carvalho@bbklaw.com	Attorneys for Plaintiffs, CITY OF SANTA ANA and THE PEOPLE OF THE STATE OF CALIFORNIA

1 I declare under penalty of perjury under the laws of the State of California that the above
2 is true and correct. Executed on April 17, 2019, at San Francisco, California.

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4
5 /s/ Kathleen A. Trempy

6 Kathleen A. Trempy
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PROOF OF SERVICE***City of Santa Ana, et al. v. Purdue Pharma, L.P. et al.
San Francisco Superior Court, Case No. CGC-19-574872***

I, the undersigned, declare as follows:

I am a citizen of the United States, over the age of 18 years, and not a party to, or interested in the within entitled action. I am employee of Covington & Burling, LLP, and my business address is Salesforce Tower, 415 Mission Street, San Francisco, CA 94105.

On April 17, 2019, I served the following document(s) on all parties in this action:

- **JOINT STIPULATION AND REQUEST TO EXTEND TIME FOR DISTRIBUTOR DEFENDANTS TO RESPOND TO COMPLAINT; [PROPOSED] ORDER**

☒ **BY ELECTRONIC SERVICE VIA FILE & SERVE XPRESS:** LexisNexis File & Serve for service on all counsel of record by electronic service pursuant to the Order Authorizing Electronic Service and pursuant to California Code of Civil Procedure § 1010.6 and California Rules of Court 2060(c). The transmission was reported as complete without error.

Roman Silberfeld Bernice Conn Michael A. Geibelson Lucas A. Messenger Robins Kaplan, LLP 2049 Century Park East, Suite 3400 Los Angeles, CA 90067 Tel.: (310) 552-0130 Fax: (310) 229-5800 rsilberfeld@robinskaplan.com bconn@robinskaplan.com mgeibelson@robinskaplan.com lmessenger@robinskaplan	Attorneys for Plaintiffs, CITY OF SANTA ANA and THE PEOPLE OF THE STATE OF CALIFORNIA
Sonia R. Carvalho Office of the City Attorney for Santa Ana 18101 Von Karman Ave, Ste. 1000 Irvine, CA 92612 Tel: (949) 263-2603 Fax: (949) 260-0972 sonia.carvalho@bbklaw.com	Attorneys for Plaintiffs, CITY OF SANTA ANA and THE PEOPLE OF THE STATE OF CALIFORNIA

1 I declare under penalty of perjury under the laws of the State of California that the above
2 is true and correct. Executed on April 17, 2019, at San Francisco, California.

3
4
5 /s/ Kathleen A. Trempy

6 Kathleen A. Trempy
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PROOF OF SERVICE***City of Santa Ana, et al. v. Purdue Pharma, L.P. et al.
San Francisco Superior Court, Case No. CGC-19-574872***

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- **JOINT STIPULATION AND REQUEST TO EXTEND TIME FOR DISTRIBUTOR DEFENDANTS TO RESPOND TO COMPLAINT; [PROPOSED] ORDER**

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Roman Silberfeld Bernice Conn Michael A. Geibelson Lucas A. Messenger Robins Kaplan, LLP 2049 Century Park East, Suite 3400 Los Angeles, CA 90067 Tel.: (310) 552-0130 Fax: (310) 229-5800 rsilberfeld@robinskaplan.com bconn@robinskaplan.com mgeibelson@robinskaplan.com lmessenger@robinskaplan	Attorneys for Plaintiffs, CITY OF SANTA ANA and THE PEOPLE OF THE STATE OF CALIFORNIA
Sonia R. Carvalho Office of the City Attorney for Santa Ana 18101 Von Karman Ave, Ste. 1000 Irvine, CA 92612 Tel: (949) 263-2603 Fax: (949) 260-0972 sonia.carvalho@bbklaw.com	Attorneys for Plaintiffs, CITY OF SANTA ANA and THE PEOPLE OF THE STATE OF CALIFORNIA

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5 /s/ Kathleen A. Trempy

6 Kathleen A. Trempy
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File & ServeXpress Transaction Receipt

File & ServeXpress Transaction ID: 63180314
Submitted by: Kathleen Trempy, Covington & Burling LLP-Palo Alto
Authorized by: Raymond Lu, Covington & Burling LLP-Palo Alto
Authorize and file on: Apr 17 2019 4:07PM PDT ⓘ
Time received by San Francisco County: Pending ⓘ

Court: CA Superior Court County of San Francisco-Civil
Division/Courtroom: N/A
Case Class: Civil-General Civil-Unlimited - \$25,001+
Case Type: Business Tort (Civil 1)
Case Number: CGC-19-574872
Case Name: City of Santa Ana et al vs Purdue Pharma LP

Transaction Option: File and Serve
Billing Reference: 022802.00099
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Courtesy Copies Sent To: Garrett Wong
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Documents List**1 Document(s)****Attached Document, 9 Pages**

Document Type:	Access:	Statutory Fee:	Linked:
Stipulation and Order	Public	\$20.00	

Document title:

Joint Stipulation and Request to Extend Time for Distributor Defendants to Respond to Complaint; [Proposed] Order

Expand All

☐ **Sending Parties (1)**

Party	Party Type	Attorney	Firm	Attorney Type
McKesson Corporation (pending)	Defendant	Lu, Raymond	Covington & Burling LLP-Palo Alto	Attorney in Charge

☐ **Recipients (3)**☐ Service List (2)

Delivery Option	Party	Party Type	Attorney	Firm	Attorney Type	Method
Service	City of Santa Ana	Plaintiff	Slberfeld, Roman	Robins Kaplan LLP	Attorney in Charge	U.S. Mail
Service	People of State of California	Plaintiff	Slberfeld, Roman	Robins Kaplan LLP	Attorney in Charge	U.S. Mail

☐ Additional Recipients (1)

Deliver To	Address
Rebecca Van Tassell	rvantassell@cov.com

☐ **Case Parties**

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Los Angeles, CA 90067

Telephone: 310 552 0130

Facsimile: 310 229 5800

Attorneys for Plaintiffs City of Santa Ana and The
People of the State of California

ELECTRONICALLY

FILED

*Superior Court of California,
County of San Francisco*

04/19/2019

Clerk of the Court

BY: JUDITH NUNEZ

Deputy Clerk

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

CITY OF SANTA ANA; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Santa Ana
City Attorney Sonia R. Carvalho,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.
SACKLER, an individual; IRENE
SACKLER LEFCOURT, an individual;
BEVERLY SACKLER, an individual and
as trustee for TRUST FOR THE BENEFIT
OF MEMBERS OF THE RAYMOND
SACKLER FAMILY; THERESA

Case No. CGC19-574872

**NOTICE OF SUBMISSION OF PETITION
FOR COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

SACKLER, an individual; DAVID A. SACKLER, an individual; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC.; ACTAVIS LLC; ALLERGAN PLC; ALLERGAN, INC.; ALLERGAN USA, INC.; INSYS THERAPEUTICS, INC.; MALLINCKRODT, PLC; MALLINCKRODT, LLC; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; MCKESSON CORPORATION; and DOES 1-100, inclusive,

Defendants.

TO EACH PARTY AND TO THE COUNSEL OF RECORD FOR EACH PARTY:

YOU ARE HEARBY NOTIFIED THAT, on April 10, 2019, Petitioners The People of the State of California, City of Costa Mesa, City of Santa Ana, City of Westminster, City of San Clemente, City of Irvine, City of Fullerton, City of El Monte, County of Alameda, and County of Kern ("Petitioners") submitted a Petition For Coordination (the "Petition") of the below actions to the Chairperson of the Judicial Counsel. The Petition requests assignment of a judge and determination whether coordination of these actions for pretrial (discovery) purposes is appropriate.

The actions sought to be coordinated are:

- a. *City of Costa Mesa, et al. v. Purdue Pharma L.P., et al.*, San Francisco Superior Court Case No. CGC-19-574865 (complaint filed on March 28, 2019);
- b. *City of Santa Ana, et al. v. Purdue Pharma L.P., et al.*, San Francisco Superior Court Case No. CGC-19-574872 (complaint filed on March 28, 2019);
- c. *City of Westminster, et al. v. Purdue Pharma L.P., et al.*, San Francisco

1 Superior Court Case No. CGC-19-574864 (complaint filed on March 28, 2019);

2 d. *City of San Clemente, et al. v. Purdue Pharma L.P., et al.*, San Francisco
3 Superior Court Case No. CGC-19-574868 (complaint filed on March 28, 2019);

4 e. *City of Irvine, et al. v. Purdue Pharma L.P., et al.*, San Francisco Superior
5 Court Case No. CGC-19-574866 (complaint filed on March 28, 2019);

6 f. *City of Fullerton, et al. v. Purdue Pharma L.P., et al.*, San Francisco Superior
7 Court Case No. CGC-19-574867 (complaint filed on March 28, 2019);

8 g. *City of El Monte, et al. v. Purdue Pharma L.P., et al.*, Los Angeles Superior
9 Court Case No. 19STCV10532 (complaint filed on March 28, 2019);

10 h. *County of Kern, et al. v. Purdue Pharma L.P., et al.*, Kern County Superior
11 Court Case No. BCV-19-100861 (complaint filed on March 27, 2019);

12 i. *County of Alameda, et al. v. Purdue Pharma L.P., et al.*, Alameda County
13 Superior Court Case No. RG19012661 (complaint filed on March 28, 2019); and

14 j. *California v. Purdue Pharma L.P., et al.*, Orange County Superior Court
15 Case No. 30-2014-00725287-CU-BT-CXC (complaint filed on May 29, 2014) (the "Orange
16 County Action").

17 The names and addresses of counsel for Petitioners are:

18 **Robins Kaplan LLP**

19 Roman Silberfeld, Bar No. (62783)

20 RSilberfeld@RobinsKaplan.com

Bernice Conn, Bar No. (161594)

21 BConn@RobinsKaplan.com

Michael A. Geibelson, Bar No. (179970)

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24 Los Angeles, CA 90067

Telephone: 310 552 0130

Facsimile: 310 229 5800

25 ///

26 ///

27 ///

28

1 **TO ANY PARTY INTENDING TO OPPOSE THE PETITION FOR**
2 **COORDINATION:**

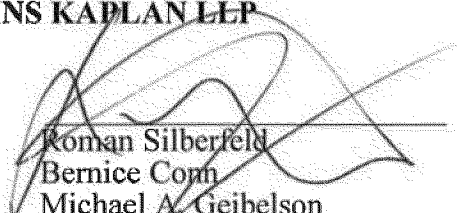
3 Pursuant to California Rules of Court, Rule 3.522 (a)(4), any party intending to oppose the
4 petition for coordination must serve and submit to the Chairperson of the Judicial Council written
5 opposition at least nine (9) court days before the hearing set in this matter.

6 A copy of the Petition and supporting documents are submitted concurrently with this
7 Notice as required by California Rules of Court, Rule 3.522(a)

8
9 Dated: April 10, 2019

ROBINS KAPLAN LLP

10 By:

11 
12 Roman Silberfeld
13 Bernice Conn
14 Michael A. Geibelson
15 Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
MINNEAPOLIS

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10 2049 Century Park East, Suite 3400
11 Los Angeles, CA 90067
12 Telephone: 310 552 0130
13 Facsimile: 310 229 5800

14 Attorneys for Plaintiffs The People of the State of
15 California, City of Costa Mesa, City of Santa Ana,
16 City of Westminster, City of San Clemente, City of
17 Irvine, City of Fullerton, City of El Monte, County
18 of Alameda, and County of Kern

11
12 SUPERIOR COURT OF THE STATE OF CALIFORNIA
13 FOR THE COUNTY OF SAN FRANCISCO
14
15

16 CITY OF COSTA MESA; and THE
17 PEOPLE OF THE STATE OF
18 CALIFORNIA, by and through Costa
19 Mesa City Attorney Kimberly Hall Barlow,

20 Plaintiffs,

21 v.

22 PURDUE PHARMA L.P.; PURDUE
23 PHARMA INC.; THE PURDUE
24 FREDERICK COMPANY; RICHARD S.
25 SACKLER, an individual and as trustee for
26 TRUST FOR THE BENEFIT OF
27 MEMBERS OF THE RAYMOND
28 SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.
SACKLER, an individual; IRENE
SACKLER LEFCOURT, an individual;
BEVERLY SACKLER, an individual and

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APR 10 2019

By _____
Coordination Attorney

Case No. CGC-19-574865

PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO STAY
OF CITY AND COUNTY OPIOID CASES;
MEMORANDUM OF POINTS AND
AUTHORITIES; DECLARATION OF
MICHAEL A. GEIBELSON

California Code of Civil Procedure § 404

VOLUME 1 OF 2

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Telephone: 310 552 0130
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8 Attorneys for Plaintiffs The People of the State of
California, City of Costa Mesa, City of Santa Ana,
9 City of Westminster, City of San Clemente, City of
Irvine, City of Fullerton, City of El Monte, County
10 of Alameda, and County of Kern

11
12 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
13 **FOR THE COUNTY OF SAN FRANCISCO**
14

15
16 CITY OF COSTA MESA; and THE
PEOPLE OF THE STATE OF
17 CALIFORNIA, by and through Costa
Mesa City Attorney Kimberly Hall Barlow,

18 Plaintiffs,

19
20 v.

21 PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
22 FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
23 TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
24 SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
25 MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
26 SACKLER, an individual; KATHE A.
SACKLER, an individual; IRENE
27 SACKLER LEFCOURT, an individual;
BEVERLY SACKLER, an individual and
28

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Judicial Council of California

APR 10 2019

By _____
Coordination Attorney

Case No. CGC-19-574865

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO STAY
OF CITY AND COUNTY OPIOID CASES;
MEMORANDUM OF POINTS AND
AUTHORITIES; DECLARATION OF
MICHAEL A. GEIBELSON**

California Code of Civil Procedure § 404

VOLUME 2 OF 2

as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual; DAVID A. SACKLER, an individual; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC.; ACTAVIS LLC; ALLERGAN PLC; ALLERGAN, INC.; ALLERGAN USA, INC.; INSYS THERAPEUTICS, INC.; MALLINCKRODT, PLC; MALLINCKRODT, LLC; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; MCKESSON CORPORATION; and DOES 1-100, inclusive,

Defendants.

CITY OF SANTA ANA; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Santa Ana City Attorney Sonia R. Carvalho, Plaintiffs,
v.
PURDUE PHARMA L.P., et al., Defendants.

Case No. CGC-19-574872

PLAINTIFFS' PETITION FOR COORDINATION AND MOTION TO STAY OF CITY AND COUNTY OPIOID CASES

California Code of Civil Procedure § 404

CITY OF WESTMINSTER; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Westminster City Attorney Richard D. Jones, Plaintiffs,
v.
PURDUE PHARMA L.P., et al., Defendants.

Case No. CGC-19-574864

PLAINTIFFS' PETITION FOR COORDINATION AND MOTION TO STAY OF CITY AND COUNTY OPIOID CASES

California Code of Civil Procedure § 404

CITY OF SAN CLEMENTE; and THE PEOPLE OF THE STATE OF

Case No. CGC-19-574868

CALIFORNIA, by and through San
Clemente City Attorney Scott C. Smith,
Plaintiffs,
v.
PURDUE PHARMA L.P., et al.,
Defendants.

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

California Code of Civil Procedure § 404

CITY OF IRVINE; and THE PEOPLE OF
THE STATE OF CALIFORNIA, by and
through Irvine City Attorney Jeffrey
Melching,
Plaintiffs,
v.
PURDUE PHARMA L.P., et al.,
Defendants.

Case No. CGC-19-574866

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

California Code of Civil Procedure § 404

CITY OF FULLERTON; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Fullerton
City Attorney Richard D. Jones,
Plaintiffs,
v.
PURDUE PHARMA L.P., et al.,
Defendants.

Case No. CGC-19-574867

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

California Code of Civil Procedure § 404

CITY OF EL MONTE; and THE PEOPLE
OF THE STATE OF CALIFORNIA, by
and through El Monte City Attorney Rick
Olivarez,
Plaintiffs,
v.
PURDUE PHARMA L.P., et al.,
Defendants.

Los Angeles County Superior Court

Case No. 19STCV10532

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

California Code of Civil Procedure § 404

COUNTY OF KERN; and THE PEOPLE
OF THE STATE OF CALIFORNIA, by
and through Kern County Counsel, Margo
Raison,
Plaintiffs,
v.
PURDUE PHARMA L.P., et al.,
Defendants.

Kern County Superior Court

Case No. BCV-19-100861

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

California Code of Civil Procedure § 404

COUNTY OF ALAMEDA; and THE
PEOPLE OF THE STATE OF

Alameda County Superior Court

CALIFORNIA, by and through Alameda
County Counsel, Donna Ziegler,
Plaintiffs,
v.
PURDUE PHARMA L.P., et al.,
Defendants.

Case No. RG19012661

**PLAINTIFFS' PETITION FOR
COORDINATION AND MOTION TO
STAY OF CITY AND COUNTY OPIOID
CASES**

California Code of Civil Procedure § 404

TO THE CHAIRPERSON OF THE JUDICIAL COUNCIL:

1. Pursuant to California Code of Civil Procedure § 404 *et seq.*, and California Rules of Court 3.501 *et seq.*, Petitioners City of Costa Mesa, City of Santa Ana, City of Westminster, City of San Clemente, City of Irvine, City of Fullerton, City of El Monte, County of Alameda, County of Kern, and The People of the State of California—plaintiffs in the above-captioned actions (collectively, the “Petitioners”)—request that a coordination motion judge be assigned to determine whether coordination is appropriate with respect to the following actions:

a. City of Costa Mesa, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574865 (complaint filed on March 28, 2019);

b. City of Santa Ana, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574872 (complaint filed on March 28, 2019);

c. City of Westminster, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574864 (complaint filed on March 28, 2019);

d. City of San Clemente, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574868 (complaint filed on March 28, 2019);

e. City of Irvine, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574866 (complaint filed on March 28, 2019);

f. City of Fullerton, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574867 (complaint filed on March 28, 2019);

g. City of El Monte, et al., v. Purdue Pharma L.P., et al., Los Angeles Superior Court Case No. 19STCV10532 (complaint filed on March 28, 2019);

h. County of Kern, et al. v. Purdue Pharma L.P., et al., Kern County Superior

1 Court Case No. BCV-19-100861 (complaint filed on March 28, 2019);

2 i. *County of Alameda, et al. v. Purdue Pharma L.P., et al.*, Alameda County
3 Superior Court Case No. RG19012661 (complaint filed on March 28, 2019); and

4 j. *California v. Purdue Pharma L.P., et al.*, Orange County Superior Court
5 Case No. 30-2014-00725287-CU-BT-CXC (complaint filed on May 29, 2014) (the “Orange
6 County Action”).

7 Together, these actions comprise the “Included Actions.” A chart listing the parties to the
8 Included Actions and their respective known attorneys of record, the status of pretrial and/or
9 discovery motions or orders, and the status of service of the complaint and summons on Defendants,
10 is attached as Exhibit A to the accompanying Declaration of Michael A. Geibelson.

11 Petitioners are a group of California cities and counties asserting claims against
12 manufacturers and distributors of prescription opioids for their contributions to the opioid
13 epidemic plaguing their communities. Petitioners have all suffered substantial economic damages
14 arising from expenses they incurred to care for the health and welfare of their citizens related to
15 and arising from their overuse, misuse, and abuse of the opioids at issue. Significantly, the
16 manufacturer and distributor defendants in the Included Actions exacerbated the opioid crisis and
17 Petitioners’ losses by, among other things, encouraging and concealing the diversion of
18 prescription opioids into the hands of drug abusers, as well as by concealing or minimizing the
19 risks of opioid abuse. Plaintiffs in the Orange County Action are not Petitioners.

20 Petitioners are represented by Robins Kaplan LLP (“Robins Kaplan”).

21 Coordinating the Included Actions before one judge for all purposes will promote the ends
22 of justice as required by California Code of Civil Procedure §§ 404 and 404.1, for the following
23 reasons:

24 a. the Included Actions assert causes of action against the same manufacturer
25 defendants (the “Manufacturer Defendants”) based on the same factual allegations, as well
26 as the same or similar theories of liability, and as such, the Included Actions will involve
27 the same or substantially overlapping facts and questions of law regarding the injuries
28 plaintiffs in the Included Actions suffered as a result of the Manufacturer Defendants’

1 actions;

2 b. Petitioners also assert related causes of action against distributor defendants
3 (the “Distributor Defendants”) and members of the Sackler family for their role in
4 overseeing the Purdue entities’ marketing and promotion of opioid products (the “Sackler
5 Defendants”), and as such, the claims against the Distributor Defendants and the Sackler
6 Defendants also will involve the same or substantially overlapping facts and questions of
7 law regarding the injuries Petitioners suffered as a result of their misconduct, which also
8 involve the same or substantially overlapping facts and questions of law regarding the
9 injuries plaintiffs have suffered in each of the Included Action as a result of the
10 Manufacturer Defendants’ conduct;

11 c. although there is no jurisdiction in federal court to hear Petitioner’s claims,
12 the United States Judicial Panel on Multidistrict Litigation has already determined that
13 claims of this type against these defendants are appropriate for coordination within the
14 federal court system—*In re: National Prescription Opiate Litigation*, United States District
15 Court for the Northern District of Ohio (Case No. 1:17-MD-2804-DAP);

16 d. coordination of the Included Actions will advance the convenience of the
17 parties, witnesses, and counsel;

18 e. the Included Actions are all in the earliest stages of litigation other than the
19 Orange County Action, which has just recently entered discovery;

20 f. coordination of the Included Actions will promote the efficient utilization of
21 judicial facilities and human resources;

22 g. coordination of the Included Actions will remove the strain of these complex
23 actions from the calendars of the various courts before which these actions are now pending;

24 h. coordination will avoid the risk of duplicative and inconsistent rulings,
25 orders, and judgments; and

26 i. coordination will increase the likelihood of settlement of the Included
27 Actions without the necessity of duplicating discovery and pre-trial proceedings in each of
28 the respective actions.

1 The Orange County Action already has been deemed a “complex case” pursuant to
2 California Rule of Court 3.400. The other Included Actions also are complex within the meaning
3 of the rule in that they require exceptional judicial management to avoid placing unnecessary
4 burdens on the courts and the litigants and to expedite the cases, keep costs reasonable, and
5 promote efficient decision making by the courts, the parties, and counsel. The other Included
6 Actions also are likely to involve numerous pretrial motions raising difficult or novel legal issues
7 that will be time consuming to resolve, management of a large number of witnesses and a
8 substantial amount of documentary evidence and coordination with related actions pending in
9 more than one Superior Court in California.

10 Other than the Orange County Action, which was initially filed in May 2014, Petitioners
11 are not aware of any other cases pending in California state court sharing common questions of
12 law or fact.

13 Pursuant to Code of Civil Procedure §§ 404 and 404.3, and California Rules of Court
14 3.521 and 3.540, Petitioners request that any hearing on this Petition and the coordinated
15 proceedings in the Included Actions be assigned to the San Francisco Superior Court. Petitioners
16 also request that the First District Court of Appeal be designated as the reviewing court in the
17 coordination action. *See* Cal. Civ. Proc. Code § 404.2; CRC 3.505.

18 If no party to any of the Included Actions serves and submits a written opposition to this
19 Petition within the time allowed by California Rule of Court 3.525, Petitioners request that this
20 Petition be granted without a hearing. If any such written opposition is timely served and
21 submitted, then Petitioners request a hearing be conducted in the San Francisco Superior Court.

22 Petitioners further request that the coordinating judge stay all proceedings in the Included
23 Actions pursuant to California Code of Civil Procedure § 404.5 and California Rule of Court
24 3.515. Staying proceedings in the Included Actions to maintain the status quo will substantially
25 reduce the risk of inconsistent and/or duplicative orders and judgments regarding the nature and
26 scope of discovery, jurisdiction, the sufficiency of the Petitioners’ allegations to withstand
27 demurrer and other dispositive motions, and other pre-trial matters.

28 This Petition is based upon this Petition, the accompanying Memorandum of Points and

1 Authorities, and the Declaration of Michael A. Geibelson and the exhibits attached thereto.

2
3 Dated: April 9, 2019

ROBINS KAPLAN LLP

4
5 By: 

Roman Silberfeld

Bernice Conn

Michael A. Geibelson

Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
MINNEAPOLIS

TABLE OF CONTENTS

	<u>Page</u>
MEMORANDUM OF POINTS AND AUTHORITIES	11
I. INTRODUCTION	11
II. THE STATUS OF THE INCLUDED ACTIONS	12
III. THE INCLUDED ACTIONS ARE COMPLEX CASES AS DEFINED BY CALIFORNIA RULE OF COURT 3.400	14
IV. COORDINATION WILL SATISFY THE REQUIREMENTS OF CCP § 404.1	15
V. CONSENT OF OTHER PARTIES.....	16
VI. HEARING ON THE PETITION	16
VII. SAN FRANCISCO COUNTY IS THE APPROPRIATE VENUE FOR THE COORDINATED ACTION	17
VIII. A STAY SHOULD BE ISSUED PENDING RESOLUTION OF THIS PETITION.....	17
IX. CONCLUSION	18
DECLARATION OF MICHAEL A. GEIBELSON	19

TABLE OF AUTHORITIES

Page(s)

Cases

McGhan Medical Corp. v. Superior Court,
11 Cal. App. 4th 804 (1992)16

Statutes

Cal. Bus. & Prof. Code § 1720314

Cal. Bus. & Prof. Code § 17026(a)14

Cal. Civ. Proc. Code § 404.116, 17, 19

Cal. Civ. Proc. Code § 404.518

Rules

Cal. R. Ct. 3.40015

Cal. R. Ct. 3.400(b)(1)15

Cal. R. Ct. 3.400(b)(2)15

Cal. R. Ct. 3.400(b)(3)16

Cal. R. Ct. 3.400(b)(5)16

Cal. R. Ct. 3.515(a)18

Cal. R. Ct. 3.52516

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Petitioners are nine California cities and counties who have suffered substantial losses arising from the plague of prescription opiate addiction afflicting their communities. Each Petitioner has filed a separate lawsuit against the same group of opiate manufacturers (the “Manufacturer Defendants”) and distributors (the “Distributor Defendants”) who have contributed to this crisis, as well as against members of the Sackler family for their role in overseeing and controlling the Purdue entities’ marketing and promotion of opioid products (the “Sackler Defendants,” and together with the Manufacturer Defendants and Distributor Defendants, the “Defendants”). Simply put, Defendants increased their profits and exacerbated the opioid crisis by, among other things, encouraging diversion of prescription opioids into the hands of drug abusers to increase their own sales, and by concealing or minimizing the risks of opioid abuse from doctors, patients, and the authorities who regulate them. As a result, Petitioners have suffered substantial damages relating to the detrimental effects that prescription opiate abuse has had on the health and welfare of their citizens.

Each of the Included Actions asserts causes of action for public nuisance and violations of California’s False Advertising Law against the same group of Manufacturer Defendants with substantially similar complaints. Each of the additional causes of action pleaded in the Included Actions regarding the Manufacturer Defendants is based on the same or substantially similar factual allegations and theories of liability. (*See* Geibelson Decl., Exs. B-K.)

As such, the Included Actions will require resolution of a substantial number of identical questions of law and fact, including, among other things, (a) the Manufacturer Defendants’ failures to warn about and disclose information concerning the prevalence, use, and abuse of opioids, and (b) whether the Manufacturer Defendants should be held liable for their part in creating the opioid epidemic and causing the resulting damage in each of the plaintiff cities and counties. Similarly, Petitioners’ complaints will require resolution of a substantial number of identical questions of law and fact with respect to the Distributor Defendants and the Sackler Defendants, including their failure to warn about and disclose information concerning the prevalence, use, and abuse of opioids,

1 and whether they should be held liable for their part in creating the opioid epidemic and causing
2 the resulting damage in each of the plaintiff cities and counties.

3 Denying coordination of these cases would result in multiple duplicative proceedings and a
4 substantial duplication of effort in each of the Included Actions and risk inconsistent results.
5 Because the interests of the courts, judicial economy, witnesses, and Plaintiffs all weigh heavily
6 against separately litigating each of the Included Actions, Petitioners respectfully request that the
7 Included Actions be coordinated before the San Francisco Superior Court.

8 **II. THE STATUS OF THE INCLUDED ACTIONS**

9 Petitioners seek coordination of the following actions (the “Included Actions”):

10 *a. California v. Purdue Pharma L.P.*, Orange County Superior Court Case No.
11 30-2014-00725287-CU-BT-CXC (complaint filed on May 29, 2014) (the “Orange County
12 Action”);

13 *b. City of Costa Mesa, et al. v. Purdue Pharma L.P., et al.*, San Francisco
14 Superior Court Case No. CGC-19-574865 (complaint filed on March 28, 2019);

15 *c. City of Santa Ana, et al. v. Purdue Pharma L.P., et al.*, San Francisco
16 Superior Court Case No. CGC-19-574872 (complaint filed on March 28, 2019);

17 *d. City of Westminster, et al. v. Purdue Pharma L.P., et al.*, San Francisco
18 Superior Court Case No. CGC-19-574864 (complaint filed on March 28, 2019);

19 *e. City of San Clemente, et al. v. Purdue Pharma L.P., et al.*, San Francisco
20 Superior Court Case No. CGC-19-574868 (complaint filed on March 28, 2019);

21 *f. City of Irvine, et al. v. Purdue Pharma L.P., et al.*, San Francisco Superior
22 Court Case No. CGC-19-574866 (complaint filed on March 28, 2019);

23 *g. City of Fullerton, et al. v. Purdue Pharma L.P., et al.*, San Francisco Superior
24 Court Case No. CGC-19-574867 (complaint filed on March 28, 2019);

25 *h. City of El Monte, et al., v. Purdue Pharma L.P., et al.*, Los Angeles Superior
26 Court Case No. 19STCV10532 (complaint filed on March 28, 2019);

27 *i. County of Kern, et al. v. Purdue Pharma L.P., et al.*, Kern County Superior
28 Court Case No. BCV-19-100861 (complaint filed on March 28, 2019); and

j. *County of Alameda, et al. v. Purdue Pharma L.P., et al.*, Alameda County Superior Court Case No. RG19012661 (complaint filed on March 28, 2019).¹

Each of the Included Actions asserts claims for public nuisance and violations of California's False Advertising Law, as well as additional, related claims based on the same set of factual allegations, against the same Manufacturer Defendants on behalf of a California city, county, and/or the People of the State of California. Additional causes of action based on the same set of factual allegations include claims for public nuisance, fraud, negligence, unjust enrichment, false advertising, negligent failure to warn, and conspiracy. While Petitioners do not currently assert claims for violation of California's Unfair Competition Law as plaintiffs did in the Orange County Action, Petitioners will amend their complaints to include this cause of action if and when they receive the required consent from their respective district attorneys. *See* Cal. Bus. & Prof. Code §§ 17203, 17026(a). The allegations against the Manufacturer Defendants in the respective complaints filed in the Included Actions are largely the same and differ only in the detail concerning the specific harms experienced in each jurisdiction.²

In addition to the Manufacturer Defendants, Petitioners assert the same causes of action, including for public nuisance, violations of California's False Advertising Law, fraud, negligence, unjust enrichment, false advertising, negligent failure to warn, and conspiracy against the same Distributor Defendants and Sackler Defendants on behalf of a California city, county, and/or the People of the State of California. Petitioners' respective complaints against the Distributor Defendants and Sackler Defendants are largely the same and differ only in the detail concerning the specific harms experienced in each jurisdiction.

Other than the Orange County Action, which was filed in May 2014, each of the Included Actions was filed and served on the majority of the Manufacturer Defendants and Distributor Defendants in late March and early April 2019. A full description of the status of service on all Defendants is available in Exhibit A to the Geibelson Declaration. Other than in the Orange County

¹ A complete list of the plaintiffs, defendants, their counsel of record (if known), and the present status of each case is detailed in Exhibit A to the accompanying declaration of Michael A. Geibelson ("Geibelson Declaration").

² Copies of Petitioners' complaints and the operative complaint in the Orange County Action are attached to the Geibelson Declaration as Exhibits B-K.

1 Action, none of the Defendants have made their initial appearance or responded to the complaints.
 2 None of the cases have been removed to federal court, and Petitioners are not aware of any valid
 3 basis for doing so because diversity is lacking and no substantial federal question (much less one
 4 that is sufficient for removal purposes) is raised by any of the causes of action.

5 In the Orange County Action, no depositions have yet taken place except for purposes of
 6 jurisdictional discovery related to Teva Pharmaceutical Industries, Ltd. The trial court in the Orange
 7 County Action is currently considering objections to various rulings by the discovery referee,
 8 including whether discovery of Defendants' personnel files should be limited to the plaintiff city
 9 and county's jurisdictions or should include the entire State of California. The Court and parties
 10 have discussed the possibility of trial bifurcation—Phase I liability, Phase II damages—though no
 11 Pretrial Order or Case Management Order has been entered as of yet. A previous trial date for the
 12 Orange County Action was recently vacated indefinitely. As a result, no trial date has been set in
 13 the Orange County Action.

14 **III. THE INCLUDED ACTIONS ARE COMPLEX CASES AS DEFINED BY**
 15 **CALIFORNIA RULE of COURT 3.400**

16 Each of the Included Actions is complex within the meaning of California Rule of Court
 17 3.400 in that they require extensive judicial management to avoid placing unnecessary burdens on
 18 the courts and the litigants and to expedite the cases, keep costs reasonable, and promote efficient
 19 decision making by the courts, the parties, and counsel. Cal. R. Ct. 3.400(b)(1)-(2). For example,
 20 the Included Actions will involve, among other things, numerous pretrial motions raising difficult
 21 and novel legal issues that will be time-consuming to resolve. (Geibelson Decl. ¶ 10.) The Included
 22 Actions also will likely involve a large number of witnesses and a substantial amount of
 23 overlapping discovery and documentary evidence concerning a lengthy period of investigation,
 24 marketing, advertising, and use of opiates by healthcare providers, including the cities' and
 25 counties' healthcare providers, as well as concerning the ancillary services provided by the cities
 26 and counties to provide services to and care for those who fell prey to opiate addiction. (Geibelson
 27 Decl. ¶ 8.)

28 Moreover, Petitioners have asserted claims against 34 separate defendants. (Geibelson Decl.

¶ 9.) Even assuming related groups of defendants (*e.g.*, the various Purdue-related entities) retain the same counsel, the Included Actions likely will require management of a large number of separately related parties. Cal. R. Ct. 3.400(b)(3).

Finally, in light of the injunctive relief sought by Petitioners in the Included Actions, there is a potential for substantial post-judgment judicial supervision. Cal. R. Ct. 3.400(b)(5).

IV. COORDINATION WILL SATISFY THE REQUIREMENTS OF CCP § 404.1

The Included Actions indisputably satisfy Section 404.1 of the California Code of Civil Procedure, which provides:

Coordination of civil actions sharing a common question of fact or law is appropriate if one judge hearing all of the actions for all purposes in a selected site or sites will promote the ends of justice taking into account whether the common question of fact or law is predominating and significant to the litigation; the convenience of parties, witnesses, and counsel; the relative development of the actions and the work product of counsel; the efficient utilization of judicial facilities and manpower; the calendar of the courts; the disadvantages of duplicative and inconsistent rulings, orders, or judgments; and, the likelihood of settlement of the actions without further litigation should coordination be denied.

Nearly every question of law or fact that can be reasonably expected to arise in the Included Actions regarding the Manufacturer Defendants will be the same, including the question of their liability. (Geibelson Decl. ¶¶ 5-6, 11-13.) At the same time, other than in the Orange County Action, nearly every question of law or fact that can be reasonably expected to arise in the Included Actions regarding the Distributor Defendants and Sackler Defendants will be the same, including the question of their liability. (*Id.*) Indeed, the only issue that foreseeably will differ between cases is the amount of damages owed to Plaintiffs. The convenience of the parties, witnesses, and counsel, as well as the need to preserve judicial resources, all favor coordination.

For example, based on their conduct in cases against plaintiffs asserting similar claims in other jurisdictions, Petitioners expect Defendants to file voluminous motions related to the pleadings, discovery, the scope of the claims at issue, and the Court's jurisdiction. In light of the imminent flood of motion practice and overlapping discovery, it would be far more efficient for all involved if these issues are resolved at the same time in all of the Included Actions, instead of in piecemeal fashion. *See McGhan Medical Corp. v. Superior Court*, 11 Cal. App. 4th 804, 814

(1992) (finding preparation for trial of similar actions “better achieved if done in a coordinated manner”). Coordination also removes the possibility of inconsistent rulings and the need for multiple appeals by ensuring uniform determination of issues in all of the cases. *See* Cal. Civ. Proc. Code § 404.1 (noting the “disadvantages of duplicative and inconsistent rulings, orders, or judgments”). Coordination will also increase the likelihood of a universal settlement of all of the Included Actions.

In addition to lessening the burden on the courts’ calendars and more efficiently utilizing judicial facilities and resources, coordination will further serve the interests of convenience to the parties, witnesses, and counsel. The Included Actions are spread over five counties in and around California. Consequently, coordination will serve the convenience of counsel who will not have to make appearances all over California, as well as serve the convenience of the parties and witnesses who, with a streamlined and organized discovery process in place, would avoid duplicative depositions.

Finally, coordination also is appropriate given the early stage of the Included Actions. Since the Included Actions were only recently filed and served, there have not yet been any appearances, scheduling conferences, or other proceedings. While the Orange County Action has been pending since 2014, it has not progressed beyond early states of discovery. (Geibelson Decl. ¶ 3, Ex. A.)

V. CONSENT OF Other PARTIES

At the time of the filing of the instant Petition, all Petitioners herein have consented to statewide coordination of the Included Actions. (Geibelson Decl. ¶ 13.)

VI. HEARING ON THE PETITION

If no party to any of the Included Actions serves and submits a written opposition to this Petition within the time allowed by California Rule of Court 3.525, Petitioners request that this Petition be granted without a hearing. If any such written opposition is timely served and submitted, then Petitioners request a hearing be conducted in the San Francisco Superior Court, should the Court deem a hearing necessary. In the event the Petition is contested and a hearing becomes necessary, San Francisco County Superior Court should be selected as the hearing site.

VII. SAN FRANCISCO COUNTY IS THE APPROPRIATE VENUE FOR THE COORDINATED ACTION

In the event the coordination judge rules on the Petition without hearing, Petitioners respectfully request coordination proceeding be assigned to San Francisco County Superior Court for the following reasons: (1) six of the total ten Included Actions are already pending in San Francisco, one action is pending in nearby Alameda County, and two of the prosecuting jurisdictions in the Orange County Action—City of Oakland and Santa Clara County—are also close to San Francisco; (2) Petitioners are informed and believe that San Francisco has sufficient facilities and judicial resources to handle this coordination; and (3) San Francisco provides an easy location for witnesses arriving to proceedings from out of town. (Geibelson Decl. ¶¶ 13-15.). Moreover, one of the most significant defendants in the action, McKesson, had its principal place of business in San Francisco through the beginning of April 2019, which is when Petitioners are informed it moved to Texas. Public filings with the California Secretary of State, however, indicate that McKesson’s principal place of business remains in San Francisco as of the date of this filing. Petitioners are further informed that even after relocation, McKesson will continue to have a strong presence in California, employing more than 1,400 people, primarily in distribution, operations, and sales. The company opened a new distribution center for its medical-surgical division in Roseville, CA earlier this year. Thus, San Francisco County provides the most convenient and logical forum for the assemblage of Plaintiffs and one of the Defendants that will figure prominently in the discovery and trial of the matters.

VIII. A STAY SHOULD BE ISSUED PENDING RESOLUTION OF THIS PETITION

To avoid duplicative proceedings and inconsistent orders, Petitioners request that the coordinating judge stay all proceedings in the Included Actions under California Code of Civil Procedure § 404.5 until the coordination process is complete. *See* Cal. R. Ct. 3.515(a) (motion for stay may be included with a petition for consolidation). Among other things, a stay will reduce unnecessary burdens on multiple different trial courts because absent a stay pending resolution of the Petition, the Included Actions (other than the Orange County Action) will be assigned judges, initial status conferences will be held, and challenges to pleadings will be made.

It also would be an inefficient use of judicial resources and contrary to the interests of justice to allow the Orange County Action to proceed during the pendency of this Petition and result in more motion practice, orders, and proceedings that will be subsequently duplicated after the Included Actions are coordinated. No prejudice will arise from such a stay here, since other than the Orange County Action, the Included Actions were only recently filed and no proceedings have yet been held. Moreover, although pending since May 2014, the Orange County Action's previous trial date was recently vacated, and as a result, no trial date has been set, which potentially could be affected by entry of a stay. Thus, a stay will effectuate the purposes of coordination, including the efficient utilization of judicial facilities and manpower, the avoidance of inconsistent rulings and orders, and the convenience of the parties and counsel. *See* Cal. Civ. Proc. Code § 404.1.

IX. CONCLUSION

For the reasons stated above, the Petition for Coordination and Motion for Stay should be granted.

Dated: April 9, 2019

ROBINS KAPLAN LLP

By: 

Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

DECLARATION OF MICHAEL A. GEIBELSON

I, Michael A. Geibelson, hereby state and declare as follows:

1. I am admitted to practice before this Court and am a Partner at the law firm of Robins Kaplan LLP, counsel for Plaintiffs and Petitioners The People of the State of California, City of Costa Mesa, City of Santa Ana, City of Westminster, City of San Clemente, City of Costa Mesa, City of Irvine, City of Fullerton, City of El Monte, County of Alameda, and County of Kern (“Petitioners”). I make this declaration in support of the instant PETITION FOR COORDINATION OF CITY AND COUNTY OPIOID CASES. If called as a witness I could competently testify to the following based upon my own personal knowledge, except where based on a review of the pleadings and records in the below “Included Actions.”

2. The Petition seeks coordination of the following actions (the “Included Actions”):

a. California v. Purdue Pharma L.P., Orange County Superior Court Case No. 30-2014-00725287-CU-BT-CXC (complaint filed on May 29, 2014) (the “Orange County Action”);

b. City of Costa Mesa, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574865 (complaint filed on March 28, 2019);

c. City of Santa Ana, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574872 (complaint filed on March 28, 2019);

d. City of Westminster, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574864 (complaint filed on March 28, 2019);

e. City of San Clemente, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574868 (complaint filed on March 28, 2019);

f. City of Irvine, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574866 (complaint filed on March 28, 2019);

g. City of Fullerton, et al. v. Purdue Pharma L.P., et al., San Francisco Superior Court Case No. CGC-19-574867 (complaint filed on March 28, 2019);

h. City of El Monte, et al., v. Purdue Pharma L.P., et al., Los Angeles Superior Court Case No. 19STCV10532 (complaint filed on March 28, 2019);

1 *i.* County of Kern, et al. v. Purdue Pharma L.P., et al., Kern County Superior
2 Court Case No. BCV-19-100861 (complaint filed on March 28, 2019); and

3 *j.* County of Alameda, et al. v. Purdue Pharma L.P., et al., Alameda County
4 Superior Court Case No. RG19012661 (complaint filed on March 28, 2019).

5 3. Other than in the Orange County Action, no discovery has been undertaken in the
6 Included Actions. Attached hereto as Exhibit A is a chart prepared by Petitioners pursuant to
7 California Rule of Court 3.521 listing the parties to the Included Actions and their respective
8 known attorneys of record, the status of pretrial or discovery motions or orders, and the status of
9 service of complaint and summons on Defendants

10 4. Attached hereto as Exhibits B-K are true and correct copies of the operative
11 complaints in the Included Actions.

12 5. The Included Actions assert causes of action for public nuisance and violations of
13 California's False Advertising Law against the same group of manufacturer defendants (the
14 "Manufacturer Defendants") based on the same allegations arising from the plague of prescription
15 opiate addiction afflicting their communities. Separate from the Orange County Action,
16 Petitioners also assert additional claims against the same Manufacturer Defendants arising from
17 the same set of factual allegations, including causes of action for public nuisance, fraud,
18 negligence, unjust enrichment, false advertising, negligent failure to warn, and conspiracy. While
19 Petitioners do not currently assert claims for violation of California's Unfair Competition Law as
20 plaintiffs did in the Orange County Action, Petitioners will amend their complaints to include this
21 cause of action if and when they receive the required consent from their respective district
22 attorneys. The Manufacturer Defendants increased their profits and exacerbated the opioid crisis
23 by, among other things, encouraging diversion of prescription opioids into the hands of drug
24 abusers to increase their own sales, and by concealing or minimizing the risks of opioid abuse
25 from doctors, patients, and the authorities who regulate them. As a result, plaintiffs in the
26 Included Actions suffered substantial damages relating to the detrimental effects that prescription
27 opiate abuse has had on the health and welfare of their citizens.

28 6. Petitioners also assert related causes of action, including for public nuisance,

violations of California’s False Advertising Law, fraud, negligence, unjust enrichment, false advertising, negligent failure to warn, and conspiracy, against distributor defendants (the “Distributor Defendants”) based on the exact same allegations arising from the plague of prescription opiate addiction afflicting their communities, and members of the Sackler family for their role in overseeing the Purdue entities’ marketing and promotion of opioid products (the “Sackler Defendants,” and together with the Manufacturer Defendants and Distributor Defendants, the “Defendants”). As such, the claims against the Distributor Defendants and the Sackler Defendants also will involve the same or substantially overlapping facts and questions of law regarding the injuries Petitioners suffered as a result of their misconduct, which also involve the same or substantially overlapping facts and questions of law regarding the injuries plaintiffs have suffered in each of the Included Actions as a result of the Manufacturer Defendants’ conduct.

7. The Orange County Action already has been designated as complex, and the other Included Actions are “complex” as that term is defined by California Rules of Court 3.400 *et seq.* Each of the Included Actions is complex because they all will they require extensive judicial management to avoid placing unnecessary burdens on the courts and the litigants and to expedite the cases, keep costs reasonable, and promote efficient decision making by the courts, the parties, and counsel. Among other things, Petitioners anticipate that each of the Included Actions will involve numerous pretrial motions raising difficult and novel legal issues that will be time-consuming to resolve.

8. Each Included Action also will likely involve a large number of witnesses and a substantial amount of overlapping discovery and documentary evidence concerning a lengthy period of investigation, marketing, advertising, and use of opiates by healthcare providers, including the cities’ and counties’ healthcare providers, as well as concerning the ancillary services provided by the cities and counties to provide services to and care for those who fell prey to opiate addiction. At the same time, litigation the Included Actions likely will require dozens of expert witnesses.

9. Petitioners asserted claims against 34 separate defendants. While Plaintiffs in nine

1 of the ten Included Actions are represented by the same counsel, each of the Included Actions
2 likely will involve management multiple separately represented defendants.

3 10. Based on their conduct in cases against plaintiffs asserting similar claims in other
4 jurisdictions, Petitioners anticipate that the Included Actions will be motion intensive, including
5 jurisdiction motions, demurrers, discovery motions, dispositive motions, and other pretrial
6 motions on scientific or other factual issues. Coordination will avoid the potential for inconsistent
7 rulings on nearly identical motions and avoid wasteful, duplicative motion practice.

8 11. Nearly every question of law or fact that can be reasonably expected to arise in the
9 Included Actions regarding the Manufacturer Defendants will be the same, including the question
10 of their liability. At the same time, other than in the Orange County Action, nearly every question
11 of law or fact that can be reasonably expected to arise in the Included Actions regarding the
12 Distributor Defendants and Sackler Defendants will be the same, including the question of their
13 liability. Petitioners anticipate that the only issue that potentially will differ between cases is the
14 amount of damages owed to Plaintiffs.

15 12. The Included Actions are currently pending in five separate counties. Coordination
16 also will serve the convenience of counsel as well as serve the convenience of the parties and
17 witnesses who, with a streamlined and organized discovery process in place, would avoid
18 duplicative depositions. So too will having one judge rule on multiple similar motions save
19 counsel from filing duplicative motions. With one pretrial judge, several courts will not have to
20 review nearly identical motions which are apt to occur on demurrers, motions to quash, and
21 discovery motions. This will help foster judicial economy and preserve valuable judicial
22 resources. Again, this case could potentially involve a number of voluminous motions, including
23 demurrers, jurisdictional motions, discovery motions, and other pretrial motions on scientific or
24 other factual issues. Coordination will avoid the potential for inconsistent rulings on nearly
25 identical motions and avoid wasteful, duplicative motion practice. Coordination will also allow
26 for an efficient pretrial process which may encourage settlement since such a process will allow
27 the parties to conserve resources while affording them an opportunity to assess all of the cases on
28 their factual merits.

13. On behalf of my clients, the Petitioners, I consent to state-wide coordination. I have not yet met and conferred with counsel for Defendants to see whether they consent to coordination since I do not know as of the timing of this filing who represents the Defendants.

14. Six of the total ten Included Actions are already pending in San Francisco, one is pending in nearby Alameda County, and two of the prosecuting jurisdictions in the Orange County Action—Oakland and Santa Clara County—are also close to San Francisco.

15. Petitioners are informed and believe that San Francisco has sufficient facilities and judicial resources coordination of the Included Actions, and that San Francisco provides an easy location for witnesses arriving to proceedings from out of town.

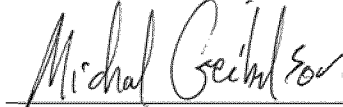
16. McKesson had its principal place of business in San Francisco at least through the beginning of April 2019, when I am informed and believe it moved its global headquarters to Texas. Public filings with the California Secretary of State, however, indicate that McKesson's principal place of business remains in San Francisco as of the date of this filing, and I am informed and believe that even after relocation, McKesson will continue to have a strong presence in California, employing more than 1,400 people, primarily in distribution, operations, and sales. The company opened a new distribution center for its medical-surgical division in Roseville, CA earlier this year.

17. A stay is necessary until the coordination process is complete to avoid potentially duplicative proceedings and inconsistent orders in the Included Actions, and therefore effectuate the purposes of coordination. Among other things, a stay will reduce unnecessary burdens on multiple different trial courts because absent a stay pending resolution of the Petition, the Included Actions (other than the Orange County Action) will be assigned judges, initial status conferences will be held, etc. It also would be an inefficient use of judicial resources and contrary to the interests of justice to allow the Orange County Action to proceed during the pendency of this Petition and result in more motion practice, orders, and proceedings that will be subsequently duplicated after the Included Actions are coordinate. No prejudice should arise from entering a stay here because other than the Orange County Action, the Included Actions were only recently filed and no proceedings have yet been held. Moreover, although pending since May 2014, the

1 Orange County Action's previous trial date was recently vacated, and as a result, no trial date has
2 been set.

3
4 I declare under penalty of perjury under the laws of the State of California that the foregoing
5 is true and correct.

6 Executed this 9th day of April, 2019, in Los Angeles, California.

7 

8 Michael A. Geibelson
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EXHIBIT A

EXHIBIT A TO DECLARATION OF MICHAEL GEIBELSON ISO OF PETITION FOR COORDINATION

Case Name	Case No.	Court Filed	Plaintiffs	Defendant Name and Name/Address of Attorney and Status of Service of Summons/Complaint	Date Filed	Status of Pretrial/ Discovery Motions and Orders
<i>City of Costa Mesa, et al. v. Purdue Pharma L.P., et al.</i>	CGC-19-574865	San Francisco County Superior Court	CITY OF COSTA MESA; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Costa Mesa City Attorney Kimberly Hall Barlow	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ KATHE A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ IRENE SACKLER LEFCOURT,¹ an individual <ul style="list-style-type: none"> ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICALS USA, INC. 	3/28/2019	None

¹ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICALS, INC. ○ (summons/complaint served, no atty appearance) ➤ JOHNSON & JOHNSON ○ (summons/complaint served, no atty appearance) ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICA, INC. ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC ○ (service pending) ➤ ALLERGAN, INC. ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
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<i>City of Santa Ana, et al. v. Purdue Pharma L.P., et al.</i>	CGC-19-574872	San Francisco County Superior Court	CITY OF SANTA ANA; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Santa Ana City Attorney Sonia R. Carvalho	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ PURDUE PHARMA INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ THE PURDUE FREDERICK COMPANY <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ MORTIMER D.A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ KATHE A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ IRENE SACKLER LEFCOURT,² an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JANSSEN PHARMACEUTICA, INC. 	3/28/2019	None
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² Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC ○ (service pending) ➤ ALLERGAN, INC. ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
<i>City of Westminster, et al. v. Purdue Pharma L.P., et al.</i>	CGC-19-574864	San Francisco County Superior Court	CITY OF WESTMINSTER; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Westminster City Attorney Richard D. Jones	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) 	3/28/2019	None

				<ul style="list-style-type: none"> ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ KATHE A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ IRENE SACKLER LEFCOURT,³ an individual <ul style="list-style-type: none"> ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC <ul style="list-style-type: none"> ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. 		
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³ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC ○ (service pending) ➤ ALLERGAN, INC. ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
<i>City of San Clemente, et al. v. Purdue Pharma L.P., et al.</i>	CGC-19-574868	San Francisco County Superior Court	CITY OF SAN CLEMENTE; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through San Clemente City Attorney Scott C. Smith	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual ○ (service pending) ➤ KATHE A. SACKLER, an individual ○ (service pending) 	3/28/2019	None

				<ul style="list-style-type: none"> ➤ IRENE SACKLER LEFCOURT,⁴ an individual <ul style="list-style-type: none"> ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC <ul style="list-style-type: none"> ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC <ul style="list-style-type: none"> ○ (service pending) ➤ ALLERGAN, INC. 		
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⁴ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
<i>City of Irvine, et al. v. Purdue Pharma L.P., et al.</i>	CGC-19-574866	San Francisco County Superior Court	CITY OF IRVINE; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Irvine City Attorney Jeffrey Melching	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual ○ (service pending) ➤ KATHE A. SACKLER, an individual ○ (service pending) ➤ IRENE SACKLER LEFCOURT,⁵ an individual ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ THERESA SACKLER, an individual ○ (service pending) 	3/28/2019	None

⁵ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JANSSEN PHARMACEUTICA, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ENDO HEALTH SOLUTIONS INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ENDO PHARMACEUTICALS INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ACTAVIS PLC <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ WATSON PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ WATSON LABORATORIES, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ACTAVIS PHARMA, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ACTAVIS LLC <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ INSYS THERAPEUTICS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ MALLINCKRODT, PLC <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ MALLINCKRODT, LLC <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ CARDINAL HEALTH, INC. <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ AMERISOURCEBERGEN CORPORATION <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ MCKESSON CORPORATION <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> 		
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<i>City of Fullerton, et al. v. Purdue Pharma L.P., et al.</i>	CGC-19-574867	San Francisco County Superior Court	CITY OF FULLERTON; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Fullerton City Attorney Richard D. Jones	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ PURDUE PHARMA INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ THE PURDUE FREDERICK COMPANY <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ MORTIMER D.A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ KATHE A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ IRENE SACKLER LEFCOURT,⁶ an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ <u>(service pending)</u> ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ <u>(summons/complaint served, no atty appearance)</u> ➤ JANSSEN PHARMACEUTICA, INC. 	3/28/2019	None
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⁶ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC ○ (service pending) ➤ ALLERGAN, INC. ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
<i>City of El Monte, et al. v. Purdue Pharma L.P., et al.</i>	19STC V10532	Los Angeles County Superior Court	CITY OF EL MONTE; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through El Monte City Attorney Rick Olivarez	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) 	3/28/2019	None

				<ul style="list-style-type: none"> ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ KATHE A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ IRENE SACKLER LEFCOURT,⁷ an individual <ul style="list-style-type: none"> ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC <ul style="list-style-type: none"> ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. 		
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⁷ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC ○ (service pending) ➤ ALLERGAN, INC. ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
<i>County of Alameda, et al. v. Purdue Pharma L.P., et al.</i>	RG190 12661	Alameda County Superior Court	COUNTY OF ALAMEDA; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Alameda County Counsel, Donna Ziegler	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual ○ (service pending) ➤ KATHE A. SACKLER, an individual ○ (service pending) 	3/28/2019	None

				<ul style="list-style-type: none"> ➤ IRENE SACKLER LEFCOURT,⁸ an individual <ul style="list-style-type: none"> ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY <ul style="list-style-type: none"> ○ (service pending) ➤ THERESA SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC <ul style="list-style-type: none"> ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC <ul style="list-style-type: none"> ○ (service pending) ➤ ALLERGAN, INC. 		
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⁸ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC ○ (service pending) ➤ MALLINCKRODT, LLC ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. ○ (service pending) ➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance) 		
<i>County of Kern, et al. v. Purdue Pharma L.P., et al.</i>	BCV-19-100861	Kern County Superior Court	COUNTY OF KERN; and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Kern County Counsel, Margo Raison	<ul style="list-style-type: none"> ➤ PURDUE PHARMA L.P. ○ (summons/complaint served, no atty appearance) ➤ PURDUE PHARMA INC. ○ (summons/complaint served, no atty appearance) ➤ THE PURDUE FREDERICK COMPANY ○ (summons/complaint served, no atty appearance) ➤ RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ MORTIMER D.A. SACKLER, an individual ○ (service pending) ➤ KATHE A. SACKLER, an individual ○ (service pending) ➤ IRENE SACKLER LEFCOURT,⁹ an individual ○ (service pending) ➤ BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY ○ (service pending) ➤ THERESA SACKLER, an individual ○ (service pending) 	3/27/2019	None

⁹ Ilene Sackler Lefcourt was inadvertently sued as “Irene Sackler Lefcourt.”

				<ul style="list-style-type: none"> ➤ DAVID A. SACKLER, an individual <ul style="list-style-type: none"> ○ (service pending) ➤ CEPHALON, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ TEVA PHARMACEUTICALS USA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JOHNSON & JOHNSON <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ JANSSEN PHARMACEUTICA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO HEALTH SOLUTIONS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ENDO PHARMACEUTICALS INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PLC <ul style="list-style-type: none"> ○ (service pending) ➤ WATSON PHARMACEUTICALS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ WATSON LABORATORIES, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS PHARMA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ACTAVIS LLC <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN PLC <ul style="list-style-type: none"> ○ (service pending) ➤ ALLERGAN, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ ALLERGAN USA, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ INSYS THERAPEUTICS, INC. <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ MALLINCKRODT, PLC <ul style="list-style-type: none"> ○ (service pending) ➤ MALLINCKRODT, LLC <ul style="list-style-type: none"> ○ (summons/complaint served, no atty appearance) ➤ CARDINAL HEALTH, INC. <ul style="list-style-type: none"> ○ (service pending) 		
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				➤ AMERISOURCEBERGEN CORPORATION ○ (summons/complaint served, no atty appearance) ➤ MCKESSON CORPORATION ○ (summons/complaint served, no atty appearance)		
<i>THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Santa Clara County Counsel James R. Williams, Orange County District Attorney Tony Rackauckas, Los Angeles County Counsel Mary C. Wickham, and Oakland City Attorney Barbara J. Parker, v. Purdue Pharma L.P., et al.</i>	30-2014-007252 87-CU-BT-CXC	Orange County Superior Court	<i>THE PEOPLE OF THE STATE OF CALIFORNIA, acting by and through Santa Clara County Counsel James R. Williams, Orange County District Attorney Tony Rackauckas, Los Angeles County Counsel Mary C. Wickham, and Oakland City Attorney Barbara J. Parker</i>	➤ PURDUE PHARMA L.P. ○ summons/complaint served ○ Attorney information: Mark S. Cheffo, Esq. DECHERT LLP Three Bryant Park 1095 Avenue of the Americas New York, NY 10036-6797 Telephone: (212) 698-3500 Facsimile: (212) 698-3599 Email: mark.cheffo@dechert.com Jae Hong Lee, Esq. Jonathan S. Tam, Esq. DECHERT LLP One Bush Street, Suite 1600 San Francisco, CA 94111 Telephone: (415) 262-4500 Facsimile: (415) 262-4555 Email: jae.lee@dechert.com, jonathan.tam@dechert.com ➤ PURDUE PHARMA INC. ○ summons/complaint served ○ Attorney information: Mark S. Cheffo, Esq. DECHERT LLP Three Bryant Park 1095 Avenue of the Americas New York, NY 10036-6797 Telephone: (212) 698-3500 Facsimile: (212) 698-3599 Email: mark.cheffo@dechert.com Jae Hong Lee, Esq. Jonathan S. Tam, Esq. DECHERT LLP One Bush Street, Suite 1600 San Francisco, CA 94111 Telephone: (415) 262-4500 Facsimile: (415) 262-4555 Email: jae.lee@dechert.com, jonathan.tam@dechert.com	<u>Original Complaint</u> 5/21/2014 <u>Operative Complaint</u> 6/8/2018	Pretrial motions to quash and orders denying those motions. Pending motion to quash on Teva Ltd. There has been discussion of pretrial procedures but no PTOs/CMOs. There are pending motions to compel, recommendations of discovery referee and objections thereto, however, Petitioners are unaware of

				<p>➤ THE PURDUE FREDERICK COMPANY</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> Mark S. Cheffo, Esq. DECHERT LLP Three Bryant Park 1095 Avenue of the Americas New York, NY 10036-6797 Telephone: (212) 698-3500 Facsimile: (212) 698-3599 Email: mark.cheffo@dechert.com <p>Jae Hong Lee, Esq. Jonathan S. Tam, Esq. DECHERT LLP One Bush Street, Suite 1600 San Francisco, CA 94111 Telephone: (415) 262-4500 Facsimile: (415) 262-4555 Email: jae.lee@dechert.com, jonathan.tam@dechert.com</p> <p>➤ TEVA PHARMACEUTICAL INDUSTRIES, LTD.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served—contested whether effective</u> ○ <u>Attorney information:</u> Collie F. James, IV, Esq. MORGAN, LEWIS & BOCKIUS LLP 5 Park Plaza, Suite 1750 Irvine, CA 92614 Telephone: (949) 399-7000 Facsimile: (949) 399-7001 Email: cjames@morganlewis.com <p>J. Gordon Cooney, Jr., Esq. Steven A. Reed, Esq. MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Telephone: (215) 963-5000 Facsimile: (215) 963-5001 Email: jgcooney@morganlewis.com, sreed@morganlewis.com</p> <p>➤ TEVA PHARMACEUTICALS USA, INC.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> Collie F. James, IV, Esq. MORGAN, LEWIS & BOCKIUS LLP 	<p>any entered discovery orders.</p> <p>No depositions have yet taken place except for purposes of jurisdictional discovery related to Teva Pharmaceutical Industries, Ltd.</p> <p>Petitioners understand that the Court and parties have discussed the possibility of trial bifurcation—Phase I liability, Phase II damages—though no Pretrial Order or Case Management Order has</p>
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				<p>5 Park Plaza, Suite 1750 Irvine, CA 92614 Telephone: (949) 399-7000 Facsimile: (949) 399-7001 Email: cjames@morganlewis.com</p> <p>J. Gordon Cooney, Jr., Esq. Steven A. Reed, Esq. MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Telephone: (215) 963-5000 Facsimile: (215) 963-5001 Email: jgcooney@morganlewis.com, sreed@morganlewis.com</p> <p>➤ CEPHALON, INC.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> Collie F. James, IV, Esq. MORGAN, LEWIS & BOCKIUS LLP 5 Park Plaza, Suite 1750 Irvine, CA 92614 Telephone: (949) 399-7000 Facsimile: (949) 399-7001 Email: cjames@morganlewis.com <p>J. Gordon Cooney, Jr., Esq. Steven A. Reed, Esq. MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Telephone: (215) 963-5000 Facsimile: (215) 963-5001 Email: jgcooney@morganlewis.com, sreed@morganlewis.com</p> <p>➤ JOHNSON & JOHNSON</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> Charles C. Lifland, Esq. Esteban Rodriguez, Esq. O'MELVENY & MEYERS 400 South Hope Street Los Angeles, CA 90071 Telephone: (213) 430-6000 Facsimile: (213) 430-6407 Email: clifland@omm.com, erodriguez2@omm.com <p>➤ JANSSEN PHARMACEUTICALS, INC.</p>	<p>been entered as of yet.</p> <p>A previous trial date for the Orange County Action was recently vacated indefinitely, and as a result, no trial date has been set.</p>
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				<p>HUESTON HENNIGAN LLP 523 West 6th Street Suite 400 Los Angeles, CA 90014 Telephone: (213) 788-4340 Facsimile: (888) 775-0898 Email: mcamp@hueston.com, mkaba@hueston.com</p> <p>Sean O. Morris Jake R. Miller Tiffany M. Ikeda ARNOLD & PORTER KAYE SCHOLER LLP 777 South Figueroa Street, 44th Floor Los Angeles, California 90017-5844 Telephone: (213) 243-4000 Facsimile: (213) 243-4199 Email: Sean.Morris@arnoldporter.com, Jake.Miller@arnoldporter.com, Tiffany.Ikeda@arnoldporter.com</p> <p>➤ ENDO PHARMACEUTICALS INC.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> John C. Hueston, Esq. HUESTON HENNIGAN LLP 620 Newport Center Drive, Suite 1300 Newport Beach, CA 92660 Telephone: (949) 229-8640 Facsimile: (888) 775-0898 Email: jhueston@hueston.com <p>Marshall A. Camp, Esq. Moez M. Kaba, Esq. HUESTON HENNIGAN LLP 523 West 6th Street Suite 400 Los Angeles, CA 90014 Telephone: (213) 788-4340 Facsimile: (888) 775-0898 Email: mcamp@hueston.com, mkaba@hueston.com</p> <p>Sean O. Morris Jake R. Miller Tiffany M. Ikeda ARNOLD & PORTER KAYE SCHOLER LLP 777 South Figueroa Street, 44th Floor Los Angeles, California 90017-5844 Telephone: (213) 243-4000</p>		
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				<p>Facsimile: (213) 243-4199 Email: Sean.Morris@arnoldporter.com, Jake.Miller@arnoldporter.com, Tiffany.Ikeda@arnoldporter.com</p> <p>➤ ACTAVIS PLC</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ Attorney information (appearances are on behalf of <u>Allergan plc f/k/a Actavis plc</u>): Ashley Neglia, Esq. KIRKLAND & ELLIS LLP 333 S. Hope Street Los Angeles, CA 90071 Telephone: (213) 680-8114 Facsimile: (213) 680-8500 Email: ashley.neglia@kirkland.com <p>Jennifer G. Levy, Esq. KIRKLAND & ELLIS LLP 655 15th Street, NW Washington, DC 20005 Telephone: (202) 879-5066 Facsimile: (202) 879-5200 Email: jennifer.levy@kirkland.com</p> <p>Timothy W. Knapp, Esq. Donna M. Welch, Esq. Martin L. Roth, Esq. KIRKLAND & ELLIS LLP 300 North LaSalle Chicago, IL 60654 Telephone: (312) 862-2000 Facsimile: (312) 862-2200 Email: timothy.knapp@kirkland.com, donna.welch@kirkland.com, martin.roth@kirkland.com</p> <p>➤ ACTAVIS INC.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ Attorney information (appearances are on behalf of <u>Allergan Finance LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc.</u>): Ashley Neglia, Esq. KIRKLAND & ELLIS LLP 333 S. Hope Street Los Angeles, CA 90071 Telephone: (213) 680-8114 Facsimile: (213) 680-8500 		
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				<p>Email: ashley.neglia@kirkland.com</p> <p>Jennifer G. Levy, Esq. KIRKLAND & ELLIS LLP 655 15th Street, NW Washington, DC 20005 Telephone: (202) 879-5066 Facsimile: (202) 879-5200 Email: jennifer.levy@kirkland.com</p> <p>Timothy W. Knapp, Esq. Donna M. Welch, Esq. Martin L. Roth, Esq. KIRKLAND & ELLIS LLP 300 North LaSalle Chicago, IL 60654 Telephone: (312) 862-2000 Facsimile: (312) 862-2200 Email: timothy.knapp@kirkland.com, donna.welch@kirkland.com, martin.roth@kirkland.com</p> <p>➤ WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ Attorney information (appearances are on behalf of <u>Allergan Finance LLC</u> f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc.): Ashley Neglia, Esq. KIRKLAND & ELLIS LLP 333 S. Hope Street Los Angeles, CA 90071 Telephone: (213) 680-8114 Facsimile: (213) 680-8500 Email: ashley.neglia@kirkland.com <p>Jennifer G. Levy, Esq. KIRKLAND & ELLIS LLP 655 15th Street, NW Washington, DC 20005 Telephone: (202) 879-5066 Facsimile: (202) 879-5200 Email: jennifer.levy@kirkland.com</p> <p>Timothy W. Knapp, Esq. Donna M. Welch, Esq. Martin L. Roth, Esq.</p>		
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				<p>KIRKLAND & ELLIS LLP 300 North LaSalle Chicago, IL 60654 Telephone: (312) 862-2000 Facsimile: (312) 862-2200 Email: timothy.knapp@kirkland.com, donna.welch@kirkland.com, martin.roth@kirkland.com</p> <p>➤ WATSON LABORATORIES, INC.</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> Collie F. James, IV, Esq. MORGAN, LEWIS & BOCKIUS LLP 5 Park Plaza, Suite 1750 Irvine, CA 92614 Telephone: (949) 399-7000 Facsimile: (949) 399-7001 Email: cjames@morganlewis.com <p>J. Gordon Cooney, Jr., Esq. Steven A. Reed, Esq. MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Telephone: (215) 963-5000 Facsimile: (215) 963-5001 Email: jgcooney@morganlewis.com, sreed@morganlewis.com</p> <p>➤ ACTAVIS LLC</p> <ul style="list-style-type: none"> ○ <u>summons/complaint served</u> ○ <u>Attorney information:</u> Collie F. James, IV, Esq. MORGAN, LEWIS & BOCKIUS LLP 5 Park Plaza, Suite 1750 Irvine, CA 92614 Telephone: (949) 399-7000 Facsimile: (949) 399-7001 Email: cjames@morganlewis.com <p>J. Gordon Cooney, Jr., Esq. Steven A. Reed, Esq. MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Telephone: (215) 963-5000 Facsimile: (215) 963-5001</p>		
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				<p>Email: jgcooney@morganlewis.com, sreed@morganlewis.com</p> <p>➤ ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.</p> <ul style="list-style-type: none">○ <u>summons/complaint served</u>○ <u>Attorney information:</u> Collie F. James, IV, Esq. MORGAN, LEWIS & BOCKIUS LLP 5 Park Plaza, Suite 1750 Irvine, CA 92614 Telephone: (949) 399-7000 Facsimile: (949) 399-7001 Email: cjames@morganlewis.com <p>J. Gordon Cooney, Jr., Esq. Steven A. Reed, Esq. MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103-2921 Telephone: (215) 963-5000 Facsimile: (215) 963-5001 Email: jgcooney@morganlewis.com, sreed@morganlewis.com</p>		
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EXHIBIT B

SUMMONS (CITACION JUDICIAL)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment form is attached)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)
ELECTRONICALLY FILED

4/2/2019
Kern County Superior Court
By Donny Alvarez, Deputy

YOU ARE BEING SUED BY PLAINTIFF: COUNTY OF KERN; and THE
(LO ESTÁ DEMANDANDO EL DEMANDANTE): PEOPLE OF THE STATE
OF CALIFORNIA, by and through Kern County Counsel
Margo Raison

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:

(El nombre y dirección de la corte es):

Kern County Superior Court
Metro Division
1415 Truxtun Avenue
Bakersfield, CA 93301

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800
Lucas A. Messenger, Bar No. 217645
ROBINS KAPLAN LLP
Los Angeles, CA 90067

DATE:

(Fecha) 4/2/2019

TAMARAH HARBER-PICKENS

Clerk, by

(Secretario)

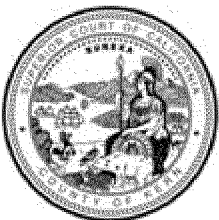
Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

[SEAL]



NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):

3. ☐ on behalf of (specify):

- under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other (specify):

4. ☐ by personal delivery on (date):

SUM-200(A)

SHORT TITLE: County of Kern, et al. v. Purdue Pharma
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

ELECTRONICALLY FILED
3/27/2019 7:59 PM
Kern County Superior Court
By Donny Alvarez, Deputy

Robins Kaplan LLP

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Attorneys for Plaintiffs County of Kern and
The People of the State of California

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF KERN

COUNTY OF KERN; and THE PEOPLE
OF THE STATE OF CALIFORNIA, by
and through Kern County Counsel Margo
Raison,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.
SACKLER, an individual; IRENE
SACKLER LEFCOURT, an individual;

Case No. BCV-19-100861

PLAINTIFFS' COMPLAINT FOR:

- 1. PUBLIC NUISANCE;**
- 2. FRAUD;**
- 3. NEGLIGENCE;**
- 4. UNJUST ENRICHMENT;**
- 5. CIVIL CONSPIRACY;**
- 6. FALSE ADVERTISING;**
- 7. NEGLIGENT FAILURE TO WARN;**
- 8. FRAUDULENT TRANSFER; and**
- 9. CIVIL CONSPIRACY**

BEVERLY SACKLER, an individual and
as trustee for TRUST FOR THE BENEFIT
OF MEMBERS OF THE RAYMOND
SACKLER FAMILY; THERESA
SACKLER, an individual; DAVID A.
SACKLER, an individual; CEPHALON,
INC.; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA
PHARMACEUTICALS USA, INC.;
JANSSEN PHARMACEUTICALS, INC.;
JOHNSON & JOHNSON; ORTHO-
MCNEIL-JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC.; ENDO
HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS INC.; ACTAVIS
PLC; WATSON PHARMACEUTICALS,
INC.; WATSON LABORATORIES, INC.;
ACTAVIS PHARMA, INC.; ACTAVIS
LLC; ALLERGAN PLC; ALLERGAN,
INC.; ALLERGAN USA, INC.; INSYS
THERAPEUTICS, INC.;
MALLINCKRODT, PLC;
MALLINCKRODT, LLC; CARDINAL
HEALTH, INC.;
AMERISOURCEBERGEN
CORPORATION; MCKESSON
CORPORATION; and
DOES 1-100, inclusive,

Defendants.

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	18
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Kern County Through Illicit Channels.....	57
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Kern County Through Illicit Channels	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Kern County	72
I.	The Statutes of Limitations Are Tolerated and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff County of Kern (hereinafter, “Kern County”) has been particularly hard hit, causing Kern County to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. Kern County, California, by and through its attorneys hereto and its Office of County Counsel, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California (the “People,” and together with Kern County, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants’ efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. Kern County has seen increased costs of, among other things, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (e)

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 public safety connected to the opioid epidemic within Kern County, including police, emergency
2 response services, and detention centers; (f) increased burden on Kern County's judicial system;
3 (g) re-education of doctors and patients about the appropriate use of opioids; and (h) extensive
4 clean-up of public parks, spaces, and facilities. At the same time, Kern County has seen a reduction
5 to tax revenues caused by the epidemic created by the Defendants. Almost every citizen of Kern
6 County has been affected. The resulting damage to Kern County was directly and foreseeably
7 caused by Defendants' actions.

8 7. These increased costs could have been—and should have been—prevented by the
9 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
10 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
11 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
12 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
13 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
14 protecting opioids from theft, misuse, and diversion.

15 8. Instead of acting with reasonable care and in compliance with their legal duties,
16 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
17 process.

18 9. At the same time, Defendants flooded the market with false statements designed to
19 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
20 claims were false.³

21 10. Defendants' actions have not only caused significant costs, but have also created a
22 palpable climate of fear, distress, dysfunction and chaos among Kern County residents where
23 opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used
24 frequently.

25 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
26 and/or unlawful conduct.

27
28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. Kern County, California, by and through its attorneys hereto and its Office of County Counsel, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. Kern County has standing to recover damage incurred because of Defendants' actions and omissions. Kern County has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical’s products and Janssen’s profits inure to J&J’s benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as “Actavis”).

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures, promotes, sells, and distributes opioids, including the branded drug Norco in the United States, including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in California with the California Secretary of State.

37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its principal place of business located in Chandler, Arizona.

38. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the United States, including California. Subsys was indicated by the FDA for the treatment of breakthrough cancer pain that other opioids could not eliminate.

39. In May 2018, an Insys sales representative admitted to taking part in a scheme to bribe physicians with purported speaking fees for marketing and education events in exchange for them prescribing Subsys for off-label uses.

40. Insys’ founder and several other former Insys executives were recently indicted by federal prosecutors on racketeering charges, alleging that these individuals approved and fostered fraudulent behavior against insurance companies and also conspired to bribe practitioners in various states. Insys Group is registered to do business in California with the California Secretary of State.

41. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

42. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S. Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital Products are registered to do business in California with the California Secretary of State.

43. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Allergan, Actavis, Insys, and Mallinckrodt are the “Manufacturer Defendants.”

C. The Distributor Defendants

44. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

45. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with Kern County and its residents, and has purposefully availed itself of the advantages of conducting business with and within Kern County. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

46. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

47. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with Kern County and its residents, and has purposefully availed itself of the advantages of conducting business with and within Kern County. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

48. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

49. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with Kern County and its residents, and has purposefully availed itself of the advantages of conducting business with and within Kern County. McKesson is in the chain of distribution of prescription opioids. McKesson

1 Corporation is registered to do business in California with the California Secretary of State.

2 50. The data which reveals and/or confirms the identity of the other wrongful opioid
3 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
4 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
5 voluntarily disclose the data necessary to identify with specificity the transactions which will form
6 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

7 51. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
8 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
9 listed on the New York Stock Exchange and their principal business consists of the nationwide
10 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
11 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
12 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
13 suspicious orders. Kern County has reason to believe each has engaged in unlawful conduct which
14 resulted in the distribution, dispensing, and diversion of prescription opioids into Kern County.
15 Kern County names each of the "Big 3" herein as defendants and places the industry on notice that
16 Kern County is acting to abate the public nuisance plaguing its community. Distributor Defendants
17 have had substantial contacts and business relationships with the People. Distributor Defendants
18 have purposefully availed themselves of business opportunities within Kern County.

19 52. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
20 Defendants."

21 **D. The Doe Defendants**

22 53. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
23 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
24 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
25 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
26 is informed and believes, and on such information and belief alleges, that each of the Defendants
27 named as a DOE is responsible in some manner for the events and occurrences alleged in this
28 Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

54. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance in Kern County, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

55. Venue is proper in this Court because Defendants transact business in California and Kern County, and some of the acts complained of occurred in this venue and the dispute arose in this venue.

IV. GENERAL FACTUAL ALLEGATIONS**A. An Overview of the Opioid Epidemic**

56. The term “opioid” includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: “Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death.”⁵

57. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as “opiates”), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

58. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander, director of Johns Hopkins University’s Center for Drug Safety and Effectiveness, “[opioids] have very, very high inherent risks . . . and there’s no such thing as a fully safe opioid.”⁶

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable->

59. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

60. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

61. The market for chronic pain patients, however, was much larger, and to take advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for chronic pain.⁷

62. As described herein, Defendants engaged in conduct that directly caused doctors to prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their obligations to prevent diversion of the highly addictive substance.

63. As a result of Defendants' wrongful conduct, the number of opioid prescriptions increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough for every person in the United States to have a bottle of pills. This represents an increase of 300% since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions were dispensed per 100 persons.

64. Many Americans, including Californians and residents of Kern County, are now addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United States, an increase of more than 22 percent over the previous year. The New York Times reported in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly

unproven-opioid-solution (last accessed December 20, 2017).

⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
2 a public health emergency by the President of the United States. The wave of opioid addiction was
3 created by the increase in prescriptions.

4 65. One in 4 Americans receiving long-term opioid therapy struggles with opioid
5 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
6 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
7 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
8 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
9 80 percent of people who use heroin first misused prescription opioids.

10 66. Drug overdose deaths among all Americans increased more than 200 percent
11 between 1999 and 2015.

12 67. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
13 there were 4,654 total opioid overdose deaths in 2016.⁹

14 ///

15 ///

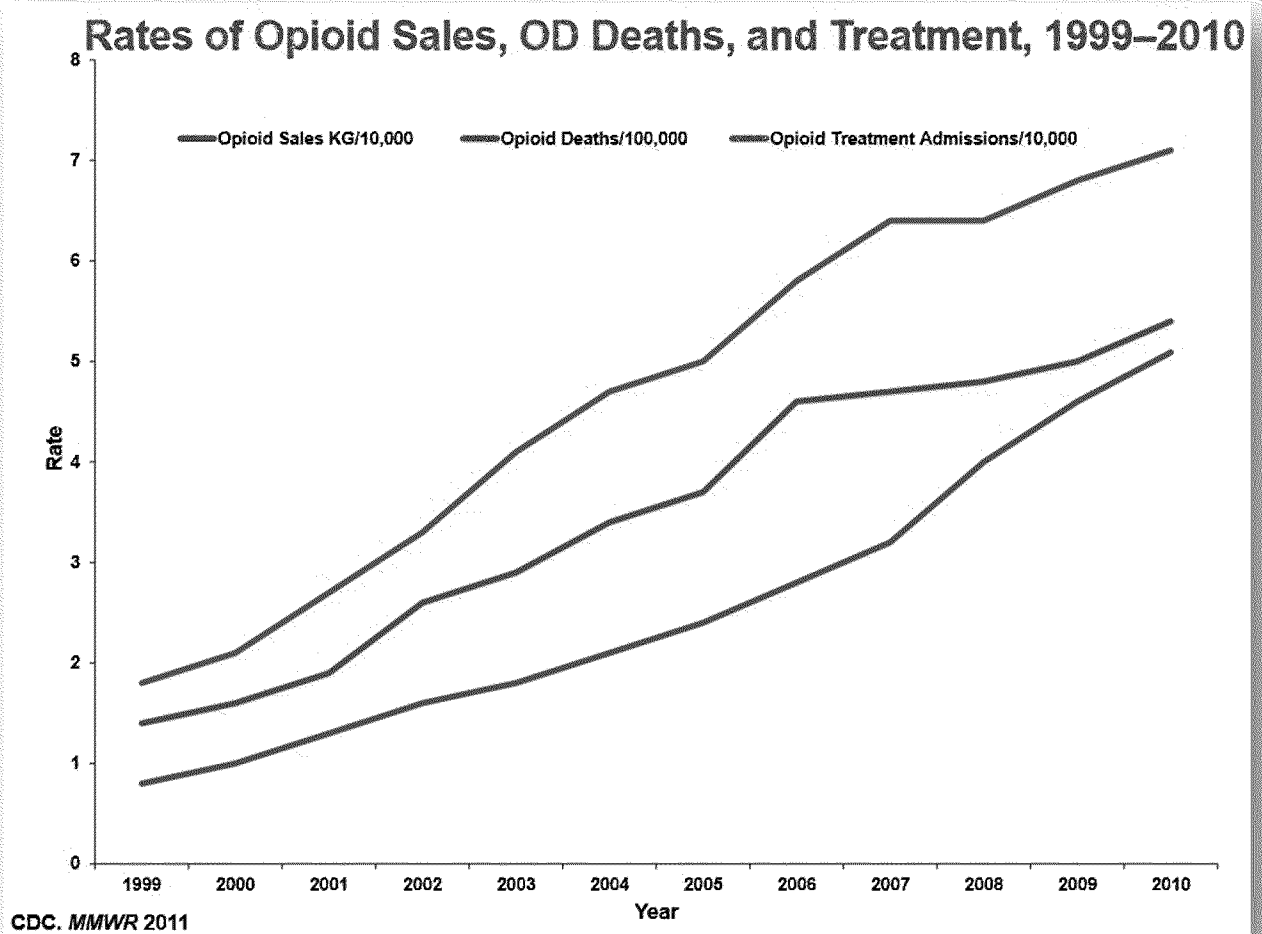
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22 68. At the same time, treatment admissions for abuse of opioids and emergency room
23 visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and
24 treatments are directly tied to the prescribing practices created by Defendants. According to the
25

26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*, N.Y.
27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
(last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



69. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

70. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on

¹⁰ U.S. Dep’t of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, *California Opioid Summary*, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

1 the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction
2 treatment, and criminal justice expenditures.¹²

3 **B. The Manufacturer Defendants Spread False or Misleading Information About**
4 **the Safety of Opioids**

5 71. Each Manufacturer Defendant developed a well-funded marketing scheme based on
6 deception to persuade doctors and patients that opioids can and should be used to treat chronic pain
7 without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients
8 who are much more likely to become addicted. In connection with this scheme, each Manufacturer
9 Defendant spent, and continues to spend, millions of dollars on promotional activities and materials
10 that falsely deny or minimize the risks of opioids.

11 72. The Manufacturer Defendants employed the same marketing plans and strategies,
12 and deployed the same messages in and around California, including in Kern County, as they did
13 nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding
14 and overseeing “core message” development on a national basis. This comprehensive approach
15 ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered
16 across marketing channels—including detailing visits, speaker events, and advertising—and in
17 each sales territory. The Manufacturer Defendants consider this high level of coordination and
18 uniformity crucial to successfully marketing their prescription drugs.

19 73. To increase the impact of their deceptive marketing schemes, on information and
20 belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that
21 the Manufacturer Defendants’ messages were consistent with one another and effective across all
22 their marketing efforts.

23 74. The deceptive marketing schemes included, among others: (a) false or misleading
24 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
25 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
26 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties

27
28 ¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
2 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
3 carried a low, or no, risk of addiction.

4 75. Contrary to the language on their drugs' labels regarding the serious risks associated
5 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
6 the serious risk of addiction; (b) created and promoted the concept of "pseudoaddiction" when signs
7 of actual addiction began appearing, and advocated that the signs of addiction should be treated
8 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
9 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
10 dosages; and (f) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent
11 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
12 opioid use, including the supposed ability of opioids to improve function and quality of life, even
13 though there was no scientifically reliable evidence to support the Manufacturer Defendants'
14 claims.

15 76. These statements were not only unsupported by or contrary to the scientific
16 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
17 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
18 patently clear that the Manufacturer Defendants' schemes were and continue to be deceptive.

19 77. The Manufacturer Defendants began their marketing schemes decades ago and
20 continue them today.

21 78. The Manufacturer Defendants' efforts have been wildly successful. Opioids are now
22 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
23 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
24 annually since 2009.¹³ In an open letter to the nation's physicians in August 2016, the U.S. Surgeon
25 General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors.
26 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
27

28 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma's Painful Medicine*, Fortune, (Nov. 9, 2011); David Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

1 for legitimate pain.”¹⁴

2 79. On information and belief, as a part of their deceptive marketing schemes, the
3 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
4 populations in the United States, including California.

5 80. For example, on information and belief, the Manufacturer Defendants focused their
6 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
7 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
8 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
9 the Manufacturer Defendants’ misrepresentations.

10 81. On information and belief, the Manufacturer Defendants also targeted vulnerable
11 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

12 82. The Manufacturer Defendants targeted these vulnerable patients even though the
13 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
14 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
15 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
16 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
17 term opioid use for elderly patients and recommended that doctors use “additional caution and
18 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
19 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
20 disorder, which interact dangerously with opioids.

21 83. The Manufacturer Defendants intentionally continued their conduct, as alleged
22 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
23 and damages alleged herein.

24 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
25 **Marketing of Opioids**

26 84. Each Manufacturer Defendant conducted, and continues to conduct, direct
27

28 ¹⁴ Murthy, supra note 3.

1 marketing consisting of advertising campaigns touting the purported benefits of their branded
2 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
3 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

4 85. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
5 benefits of opioids for chronic pain. For example:

- 6 a. Endo, on information and belief, has distributed and made available on its website
7 opana.com a pamphlet promoting Opana ER with photographs depicting patients
8 with physically demanding jobs like construction worker and chef, misleadingly
9 implying that the drug would provide long-term pain-relief and functional
10 improvement.
- 11 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
12 for OxyContin in 2012 in medical journals. These ads featured chronic pain
13 patients and recommended OxyContin for each. One ad described a "54-year-old
14 writer with osteoarthritis of the hands" and implied that OxyContin would help the
15 writer work more effectively.

16 86. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
17 misleading representations in New York, they continued to disseminate them elsewhere throughout
18 the United States, including California.

19 87. The direct advertising disseminated by the Manufacturer Defendants failed to
20 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
21 support many of their claims.

22 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**

23 **to Spread False and Misleading Information About Opioids**

24 88. Each Manufacturer promoted the use of opioids for chronic pain through
25 "detailers"—sophisticated and specially trained sales representatives who visited individual doctors
26 and medical staff in their offices—and small group speaker programs.

27 89. The Manufacturer Defendants invested heavily in promoting the use of opioids for
28 chronic pain through detailers and small group speaker programs.

90. The Manufacturer Defendants devoted massive resources to direct sales contacts
with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what

1 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
2 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
3 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

4 91. On information and belief, these detailers have spread and continue to spread
5 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
6 including thousands of doctors in California, in the following manner:

- 7 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 8 b. Describe their opioid products as “steady state” – falsely implying that these
9 products are less likely to produce the high and lows that fuel addiction – or as
10 less likely to be abused or result in addiction;
- 11 c. Tout the effectiveness of screening or monitoring patients as a strategy for
12 managing opioid abuse and addiction;
- 13 d. State that there is no maximum dose and that doctors can safely increase doses
14 without disclosing the significant risks to patients at higher doses;
- 15 e. Discuss “pseudoaddiction;”
- 16 f. State that patients would not experience withdrawal if they stopped using their
17 opioid products; and
- 18 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
19 harder to abuse or misuse.

20 92. Because these detailers must adhere to scripts and talking points drafted by the
21 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
22 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
23 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
24 corrected this misinformation.

25 93. The Manufacturer Defendants’ detailing to doctors was highly effective in
26 generating the national proliferation of prescription opioids. On information and belief, the
27 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
28 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
targeting, customizing, and monitoring of their marketing efforts.

94. The Manufacturer Defendants also identified doctors to serve on their speakers’

bureaus in exchange for payment and other remuneration, as well as attend programs with speakers and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were in fact presenting a script prepared by the Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids, including addiction risks.

95. Each Manufacturer Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo, and \$2 million by Actavis.

96. Marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. On information and belief, more frequent prescribers are generally more likely to have received a detailing visit, and in some instances, more infrequent prescribers of opioids received a detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer Defendant's opioid products.

97. The FDA has cited at least one Manufacturer Defendant for deceptive promotions used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that certain brochures distributed by Actavis were "false or misleading because they omit and minimize the serious risks associated with [Kadian], broaden and fail to present the limitations to the approved indication of the drug, and present unsubstantiated superiority and effectiveness claims." The FDA also found that "[t]hese violations are a concern from a public health perspective because they suggest that the product is safer and more effective than has been demonstrated."¹⁵

¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December 29, 2017).

1 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 2 **Seemingly Independent Third Parties that Disseminated Unbranded**
 3 **Advertising Created by the Manufacturer Defendants**

4 98. The Manufacturer Defendants also deceptively marketed opioids in California
 5 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 6 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 7 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 8 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 9 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 10 promote opioids for the treatment of chronic pain as non-addictive.

11 99. The extent of the financial ties between the opioid industry and third-party advocacy
 12 groups is stunning. A recent report released by the United State Senate Homeland Security and
 13 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 14 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 15 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 16 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 17 messaging.” The report concluded that “many of the groups described in this report may have
 18 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

19 100. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 20 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 21 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 22 advertising to give the false appearance that the deceptive messages came from an independent and
 23 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
 24 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
 25 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

26 _____
 27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 101. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
2 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
3 unbranded advertising stated that “People who take opioids as prescribed usually do not become
4 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
5 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
6 medical use.”

7 102. In addition to using third parties to disguise the source of their misinformation
8 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
9 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
10 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
11 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
12 Defendants because their public positions supported the use of opioids to treat chronic pain.

13 103. Manufacturer Defendants paid these KOLs to serve as consultants or on their
14 advisory boards and to give talks or present continuing medical education programs (CMEs), and
15 their support helped these KOLs become respected industry experts. As they rose to prominence,
16 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
17 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
18 became dependent on continuing to promote a pro-opioid message.

19 104. Pro-opioid doctors like the KOLs are one of the most important avenues that the
20 Manufacturer Defendants use to spread their false and misleading statements about the risks and
21 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
22 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
23 and reliable support for treatment of chronic pain through chronic opioid therapy without
24 significant risk of addiction.

25 105. For example, the New York Attorney General (“NY AG”) found in its settlement
26 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
27
28

1 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
2 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
3 objectivity of the testimonials.

4 106. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
5 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
6 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
7 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
8 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
9 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
10 opioid therapy that acknowledged risks of addiction.

11 107. The Manufacturer Defendants' KOLs also served on committees that developed
12 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
13 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
14 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
15 were created, and they are not supported by the scientific evidence today. Defendants were able to
16 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
17 Guideline recognizes that treatment guidelines can "change prescribing practices."

18 108. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
19 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
20 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
21 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
22 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
23 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
24 "destigmatize" opioid. Dr. Portenoy conceded that "[d]ata about the effectiveness of opioids does
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
2 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
3 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

4 109. Dr. Portenoy also made frequent media appearances promoting opioids and
5 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
6 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
7 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
8 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
9 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
10 personal history, of substance abuse, and does not have a history in the family of substance abuse,
11 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
12 person is not going to become addicted.”¹⁹

13 110. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
14 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
15 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
16 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
17 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
18 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
19 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
20 including nearly \$2 million from Cephalon.

21 111. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
22 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
23 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
24 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
25 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
2 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
3 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
4 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
5 their influence and control.

6 112. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
7 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
8 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
9 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
10 doctors in Kern County and doctors treating residents of Kern County.²⁰

11 113. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
12 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
13 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
14 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
15 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
16 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
17 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
18 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
19 to give patients more medication."²²

20 114. On information and belief, the Manufacturer Defendants also entered into
21 arrangements with seemingly unbiased and independent patient and professional organizations to
22 promote opioids for the treatment of chronic pain. Under the direction and control of the
23 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
24 American Pain Foundation ("APF")²³ and the American Academy of Pain Medicine—generated

25
26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

27 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

28 ²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

²³ Dr. Portenoy was a member of the board of the APF.

1 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
2 evidence did not support these guidelines, materials, and programs at the time they were created,
3 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
4 the 2016 CDC Guideline.

5 115. The Manufacturer Defendants worked together through Front Groups to spread their
6 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
7 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
8 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
9 on behalf of both the opioid industry and the Front Groups.

10 116. On information and belief, these Front Groups also assisted the Manufacturer
11 Defendants by responding to negative articles, advocating against regulatory or legislative changes
12 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
13 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

14 117. These Front Groups depended on the Manufacturer Defendants for funding and, in
15 some cases, for their very survival. On information and belief, the Manufacturer Defendants
16 exercised control over programs and materials created by these groups by collaborating on, editing,
17 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
18 Defendants made sure that the Front Groups would only generate messages the Manufacturer
19 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
20 experts serving the needs of their members, whether patients suffering from pain or doctors treating
21 those patients.

22 118. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
23 including many of the same ones. Several of the most prominent Front Groups are described in
24 greater detail below, but there are many others, including the American Pain Society, American
25 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,
26 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

27
28 ²⁴ See Neuman & Kodjack, *supra* note 16.

²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E.

119. Organizations, including the U.S. Senate Finance Committee, began to investigate the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise, between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and “its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic circumstances.”

120. Another one of the Front Groups for the Manufacturer Defendants was the American Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants’ deceptive marketing of chronic opioid therapy.

121. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended these annual events.

122. On information and belief, AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM

Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*, Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
2 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
3 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
4 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
5 investigation.

6 123. The Manufacturer Defendants were able to influence AAPM through both their
7 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

8 124. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
9 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
10 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
11 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
12 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
13 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

14 125. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
15 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
16 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
17 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
18 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
19 practices, but they also are cited throughout the scientific literature and referenced by third-party
20 payors in determining whether they should cover treatments for specific indications.
21 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
22 guidelines with doctors during individual sales visits.

23 126. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
24 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,
25 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
26

27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American*
Academy of Pain Medicine and the American Pain Society, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer*
Pain, 10 *J. Pain* 113 (2009).

1 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 2 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 3 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 4 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 5 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 6 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 7 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 8 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 9 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 10 disseminated in Kern County during the relevant time period, are still available online, and were
 11 often reprinted in the Journal of Pain, which is the official journal of the American Pain Society.
 12 The Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 13 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 14 Defendants' financial support to members of the panel.

15 127. On information and belief, the Manufacturer Defendants combined their efforts
 16 through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised
 17 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 18 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 19 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 20 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 21 worked to address a lack of coordination among its members and develop cohesive industry
 22 messaging.

23 128. On information and belief, through Front Groups and KOLs, the Manufacturer
 24 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 25 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 26 addiction.

27
 28 ²⁹ *Id.*

129. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use.

C. The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False

130. To convince doctors and patients that opioids carry a low risk of addiction, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC conclusively debunked.

131. These misrepresentations reinforced each other and created the dangerously misleading impressions, among others, that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

132. Some examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed December 19, 2017).

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Kern County, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

133. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

134. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

135. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive

³¹ Available at, <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*,

evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

136. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

137. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

138. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its

Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No.

www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not to “make statements that ... opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. This prohibition did not extend to California.

139. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is *under-treated* . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated.”

15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long acting opioid.
- f. Details for Purdue have directed doctors and their medical staffs in California, including in Kern County, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.
- g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which states: “Pseudo-addiction describes patient behaviors that may occur when pain is undertreated...Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.”

Deceptive Claims of Pseudoaddiction

140. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

141. In connection with its 2016 settlement with the NY AG, Endo was forced to admit that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents” and reported that despite the fact that Endo trained its sales representative to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement

³⁷ See *supra* note 35, at 7.

1 with respect to California.

2 142. The Manufacturer Defendants also falsely instructed doctors and patients that
3 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
4 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
5 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
6 general practitioners and family doctors who lack the time and expertise to closely manage higher-
7 risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel
8 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
9 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
10 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 11 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
12 *Family Practice* written by a doctor who became a member of Endo's speakers
13 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
14 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
tools, claiming that patients at high risk of addiction could safely receive
chronic opioid therapy using a "maximally structured approach" involving
toxicology screens and pill counts.
- 15 b. On information and belief, Purdue sponsored a November 2011 webinar,
16 *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed
that screening tools, urine tests, and patient agreements prevent "overuse of
prescriptions" and "overdose deaths."
- 17 c. On information and belief, as recently as 2015, Purdue has represented in
18 scientific conferences that "bad apple" patients – and not opioids – are the
19 source of the addiction crisis and that once those "bad apples" are identified,
doctors can safely prescribe opioids without causing addiction.
- 20 d. On information and belief, detailers for the Manufacturer Defendants have
21 touted and continue to tout to doctors in California, including Kern County the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

22 143. Once again, the 2016 CDC Guideline confirms that these types of statements were
23 false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
24 The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk
25 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
26 widely believed by doctors to detect and deter abuse—"for improving outcomes related to
27 overdose, addiction, abuse, or misuse." As a result, the 2016 CDC Guideline recognizes that
28

1 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
2 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
3 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

4 144. To underplay the risk and impact of addiction and make doctors feel more
5 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
6 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
7 failed to disclose the increased difficulty of stopping opioids after long-term use.

8 145. For example, on information and belief, a 2011 non-credit educational program
9 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
10 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

11 146. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
12 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
13 by gradually decreasing the dose of medication during discontinuation” without mentioning any
14 hardships that might occur.³⁸ This publication was available on APF’s website until the
15 organization dissolved in May 2012.

16 147. Detailers for Janssen have told and continue to tell doctors in California, including
17 Kern County, that their patients would not experience withdrawal if they stopped using opioids.

18 **Deceptive Minimization of Opioid Withdrawal**

19 148. The Manufacturer Defendants also deceptively minimized the significant symptoms
20 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
21 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
22 understated the difficulty of tapering, particularly after long-term opioid use.

23 149. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline
24 recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]”
25 to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,”
26 because “physical dependence on opioids is an expected physiologic response in patients exposed

27
28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

1 to opioids for *more than a few days.*” (Emphasis added.) The 2016 CDC Guideline states that
 2 “more than a few days of exposure to opioids significantly increases hazards” and “each day of
 3 unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The
 4 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years
 5 on high dosages because of physical and psychological dependence” and highlights the difficulties,
 6 including the need to carefully identify “a taper slow enough to minimize symptoms and signs of
 7 opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The
 8 CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of
 9 different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

10 **Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk**

11 150. The Manufacturer Defendants also falsely claimed that doctors and patients could
 12 increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to
 13 patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer
 14 Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this
 15 misrepresentation, doctors would have abandoned treatment when patients built up tolerance and
 16 lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that
 17 were made by, and are continuing to be made by Defendants, are described below:

- 18 a. On information and belief, Actavis’s predecessor created a patient brochure for
 19 Kadian in 2007 that stated, “Over time, your body may become tolerant of
 20 your current dose. You may require a dose adjustment to get the right amount
 21 of pain relief. This is not addiction.” Upon information and belief, based on
 22 Actavis’ acquisition of its predecessor’s marketing materials along with the
 23 rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- 24 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for
 25 People Living with Pain* (2007), which claims that some patients “need” a
 26 larger dose of an opioid, regardless of the dose currently prescribed. The guide
 27 stated that opioids have “no ceiling dose” and are therefore the most
 28 appropriate treatment for severe pain. This guide is still available online.³⁹
- c. Endo sponsored a website, “PainKnowledge,” which, upon information and
 belief, claimed in 2009 that opioid dosages may be increased until “you are on
 the right dose of medication for your pain.”

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
 accessed December 19, 2017).

- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120), on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased... You won't 'run out' of pain relief."⁴⁰
- e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. On information and belief, through March 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue's detailers have told doctors in California, including in Kern County that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

151. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explained in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explained that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir. Sept. 8, 2005).

1 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
2 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
3 morphine milligram equivalents per day.

4 152. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
5 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
6 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
7 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
8 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
9 opioid-related overdose were initially prescribed opioids for chronic pain.

10 **Deceptive Advertising of Abuse Deterrent Opioids**

11 153. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
12 properties of some of their opioid formulations also has created false impressions that these opioids
13 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
14 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
15 addictive.

16 154. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
17 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
18 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
19 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
20 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
21 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
22 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
23 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
24 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term
25 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
26 Director of the CDC, has further reported that his staff could not find “any evidence showing the
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28

1 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

2 155. Because of these significant limitations on AD opioids, as well as the heightened
3 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
4 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
5 be truthful and not misleading (based on a product’s labeling), and supported by sound science
6 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
7 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

8 156. Despite this lack of evidence, the Manufacturer Defendants have made and continue
9 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
10 to prevent or reduce abuse and addiction and the safety of these formulations.

11 157. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
12 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
13 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was *no* evidence that
14 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
15 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
16 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
17 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
18 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
19 including doctors in Kern County, that Opana ER is harder to abuse and given demonstrations to
20 nurse practitioners about Opana ER’s purported abuse deterrent properties.

21 158. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements
22 in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those
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24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-
push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou
ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

1 statements to be false and misleading because there was no difference in the ability to extract the
2 narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge
3 of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy
4 benefit managers.

5 159. Because Orpana ER could be “readily prepared for injection” and was linked to
6 outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that
7 Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on
8 June 8, 2017, and requested that Endo withdraw Opana ER from the market.

9 160. Likewise, Purdue has engaged and continues to engage in deceptive marketing of
10 its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not
11 market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and
12 believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-
13 called abuse deterrent properties of Purdue’s opioid products as a primary selling point to
14 differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim
15 that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim
16 that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to
17 yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids
18 are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral
19 abuse or misuse, and that its abuse deterrent properties can be defeated.

20 161. These statements and omissions by Purdue are false and misleading, and conflict
21 with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates
22 that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent
23 properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent
24 properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD
25 opioids prevent or reduce abuse, misuse, or diversion.

26 162. Purdue knew and should have known that reformulated OxyContin is not better at
27 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
28 2015 study also shows that many opioid addicts are abusing Purdue’s AD opioids through oral

1 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 2 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 3 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 4 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 5 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 6 being abused in large numbers.⁴⁶

7 163. Testimony in litigation against Purdue and other evidence indicates that Purdue
 8 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 9 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 10 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 11 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 12 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 13 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 14 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 15 opioid products.

16 164. The development, marketing, and sale of AD opioids is a continuation of the
 17 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 18 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 19 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 20 expensive than other opioid products even though they provide little or no additional benefit in the
 21 prevention of opioid abuse.

22 165. These false and misleading claims about the abuse deterrent properties of their
 23 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 24 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 430.

27 ⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose*
 28 *epidemic*, Business Insider (Mar. 14, 2016), available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed December 20, 2017).

believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its earlier sins (even though its true motive was to preserve the profits it otherwise would have lost when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit in the prevention of opioid abuse.

166. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy

167. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was significant upside to long-term opioid use.

168. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

169. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.”

170. Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these

1 false and misleading claims, but they have continued to make them today.

2 171. For example, the Manufacturer Defendants falsely claimed that long-term opioid
3 use improved patients' function and quality of life. Some illustrative examples of these deceptive
4 claims that were made by, and are continuing to be made by Defendants are described below:

- 5 a. On information and belief, Actavis distributed an advertisement that claimed
6 that the use of Kadian to treat chronic pain would allow patients to return to
7 work, relieve "stress on your body and your mental health," and help patients
8 enjoy their lives.
- 9 b. Endo distributed advertisements that claimed that the use of Opana ER for
10 chronic pain would allow patients to perform demanding tasks like
11 construction work or work as a chef and portrayed seemingly healthy,
12 unimpaired subjects.
- 13 c. On information and belief, Janssen sponsored and edited a patient education
14 guide entitled *Finding Relief: Pain Management for Older Adults* (2009) –
15 which states as "a fact" that "opioids may make it easier for people to live
16 normally." The guide lists expected functional improvements from opioid use,
17 including sleeping through the night, returning to work, recreation, sex,
18 walking, and climbing stairs and states that "[u]sed properly, opioid
19 medications can make it possible for people with chronic pain to 'return to
20 normal.'"
- 21 d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo
22 and Purdue, taught that relief of pain by opioids, by itself, improved patients'
23 function. The book remains for sale online.
- 24 e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by
25 Cephalon and Purdue, counseled patients that opioids "give [pain patients] a
26 quality of life we deserve." This publication is still available online.
- 27 f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids,
28 "your level of function should improve; you may find you are now able to
participate in activities of daily living, such as work and hobbies, that you were
not able to enjoy when your pain was worse." Elsewhere, the website touted
improved quality of life (as well as "improved function") as benefits of opioid
therapy. The grant request that Endo approved for this project specifically
indicated NIPC's intent to make misleading claims about function, and Endo
closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational
programs titled *Persistent Pain in the Older Patient*, which claimed that chronic
opioid therapy has been "shown to reduce pain and improve depressive
symptoms and cognitive functioning." The CME was disseminated via
webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website,
Let's Talk Pain, in 2009, which featured an interview edited by Janssen
claiming that opioids allowed a patient to "continue to function." This video is
still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in California, including in Kern County, the message that opioids will improve patient function.

172. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"
- b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

173. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

174. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won't Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

1 FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical
2 experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating
3 pain, taken together with any drug-related side effects patients may experience ... results in any
4 overall positive impact on a patient’s work, physical and mental functioning, daily activities, or
5 enjoyment of life.”⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making
6 it publicly clear “that [the claim that] patients who are treated with the drug experience an
7 improvement in their overall function, social function, and ability to perform daily activities . . .
8 has not been demonstrated by substantial evidence or substantial clinical experience.”

9 175. The Manufacturer Defendants also falsely and misleadingly emphasized or
10 exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look
11 to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants
12 frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of
13 analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer
14 Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from
15 opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and
16 have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious
17 risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene
18 pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed,
19 the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids
20 should only be used as a last resort “in patients for which alternative treatment options” like non-
21 opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids,
22 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

23 176. In addition, Purdue has misleadingly promoted OxyContin as being unique among
24

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm’n’s, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
 2 believes that Purdue's detailers have told prescribers in California within the last two years that
 3 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
 4 fact that Purdue has known at all times relevant to this action. Upon information and belief,
 5 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
 6 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
 7 40% of their active medicine immediately, after which release tapers. This triggers a powerful
 8 initial response, but provides little or no pain relief at the end of the dosing period, when less
 9 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
 10 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
 11 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
 12 OxyContin more dangerous because the declining pain relief patients experience toward the end of
 13 each dosing period drives them to take more OxyContin before the next dosing period begins,
 14 quickly increasing the amount of drug they are taking and spurring growing dependence.

15 177. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
 16 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
 17 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
 18 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
 19 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
 20 Fentora for the treatment of chronic pain because of the potential harm.

21 178. Despite this, Plaintiff is informed and believes that Cephalon conducted and
 22 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
 23 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this
 24 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
 25 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
 26

27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
 28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
 2017).

1 effective for treating non-cancer, chronic pain.

2 179. Cephalon's deceptive marketing gave doctors and patients the false impression that
3 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
4 by the FDA for such uses. For example:

- 5 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
6 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
7 News in 2009. The CME instructed doctors that "[c]linically, broad
8 classification of pain syndromes as either cancer- or non-cancer-related has
9 limited utility" and recommended Actiq and Fentora for patients with chronic
10 pain.
- 11 b. Upon information and belief, Cephalon's sales representatives set up hundreds
12 of speaker programs for doctors, including many non-oncologists, which
13 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 14 c. In December 2011, Cephalon widely disseminated a journal supplement
15 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
16 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
17 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
18 and Pain Medicine News – three publications that are sent to thousands of
19 anesthesiologists and other medical professionals. The Special Report openly
20 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

21 180. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
22 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
23 representatives have told doctors that in California that they will no longer be asked to give paid
24 talks unless they increase their prescribing of Purdue's drugs.

25 181. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
26 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
27 of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
28 unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

182. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of
thousands of doctors in California and could identify California doctors who displayed red flags
for diversion, including doctors whose waiting rooms were overcrowded, parking lots had

1 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
2 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
3 prescribing its drugs.

4 183. Incredibly, rather than report these doctors to state medical boards or law
5 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
6 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
7 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
8 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
9 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
10 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
11 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
12 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
13 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
14 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
15 so, Purdue protected its own profits at the expense of public health and safety.

16 184. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
17 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
18 those prescribers even after they were placed on a “no-call” list.

19 185. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
20 Services, said in a Los Angeles Times article, “Any drug company that has information about
21 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
22 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
23 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
24 Purdue continues to profit from the prescriptions by such prolific prescribers.

25 186. Like Purdue, Endo has been cited for its failure to set up an effective system for
26 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY
27 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
28 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers

1 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
2 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
3 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
4 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
5 could have recognized potential signs of diversion and reported those prescribers but failed to do
6 so.

7 187. The Manufacturer Defendants made, promoted, and profited from their
8 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
9 that their misrepresentations were false and misleading. The history of opioids, as well as research
10 and clinical experience over the last 20 years, established that opioids were highly addictive and
11 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
12 access to scientific studies, detailed prescription data, and reports of adverse events, including
13 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
14 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
15 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
16 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
17 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
18 same misrepresentations described in this Complaint.

19 188. On information and belief, the Manufacturer Defendants coordinated their
20 messaging through national and regional sales and speaker trainings and coordinated
21 advertisements and marketing materials.

22 189. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
23 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
24 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
25 therapy by funding and working through third parties like Front Groups and KOLs. The
26 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and
27 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
28 Defendants' false and misleading statements about the risks and benefits of long-term opioid use

1 for chronic pain.

2 190. Manufacturer Defendants also never disclosed their role in shaping, editing, and
3 approving the content of information and materials disseminated by these third parties.
4 Manufacturer Defendants exerted considerable influence on these promotional and “educational”
5 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
6 companies that were not, and have not yet become, public. For example, painknowledge.org, which
7 is run by the NIPC, did not disclose Endo’s involvement. Other Manufacturer Defendants, such as
8 Purdue and Janssen, ran similar websites that masked their own direct role.

9 191. Finally, the Manufacturer Defendants manipulated their promotional materials and
10 the scientific literature to make it appear that the information and materials disseminated by third
11 parties were accurate, truthful, and supported by objective evidence when they were not. The
12 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
13 evidence for propositions the studies did not support. The lack of support for the Manufacturer
14 Defendants’ deceptive messages was not apparent to medical professionals who relied upon them
15 in making treatment decisions, nor could it have been detected by Kern County.

16 192. The Manufacturer Defendants’ efforts to artificially increase the number of opioid
17 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
18 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and
19 has increased in parallel with [opioid] overdoses.”⁵¹ Many abusers start with legitimate
20 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
21 for chronic pain are critical “[t]o reverse the epidemic of opioid drug overdose deaths and prevent
22 opioid-related morbidity.”⁵² Accordingly, the Manufacturer Defendants’ false and misleading
23 statements directly caused the current opioid epidemic. The Manufacturer Defendants’
24 misrepresentations deceived and continue to deceive doctors and patients in California, including
25 in Kern County, about the risks and benefits of long-term opioid use. California doctors confirm

26 _____
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
28 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

⁵² *Id.*

1 this. Studies also reveal that many doctors and patients are not aware of or do not understand these
2 risks and benefits. Indeed, patients often report that they were not warned they might become
3 addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than
4 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.
5 Plaintiff is informed and believes that California residents were never told that they might become
6 addicted to opioids when they started taking them, were told that they could easily stop using
7 opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

8 193. Numerous doctors and substance abuse counselors in California note that many of
9 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
10 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
11 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
12 for opioid addiction.

13 194. The Manufacturer Defendants knew and should have known that their
14 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
15 when they made them.

16 195. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
17 properties of their opioids caused and continue to cause doctors in California, including doctors in
18 Kern County, to prescribe opioids for chronic pain conditions such as back pain, headaches,
19 arthritis, and fibromyalgia, rather than prescribing less addictive medications. Absent
20 Manufacturers Defendants' deceptive marketing scheme, these doctors would not have prescribed
21 as many opioids to as many patients, and there would not have been as many opioids available for
22 misuse and abuse or as much demand for those opioids.

23 196. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
24 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
25 California, including in Kern County. Opioids are the most common means of treatment for chronic
26 pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per
27 year are prescribed a long-acting opioid.

28 197. In California, including Kern County, Manufacturer Defendants' deceptive

1 marketing of the abuse-deterrent properties of their opioids during the past few years has been
2 particularly effective. For example, one survey reports that pain specialists were more likely to
3 recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically
4 because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent
5 properties were using more of it than those who did not know it was an AD opioid. Although sales
6 of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold
7 in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or
8 approximately 25% in opioid sales revenue in 2015).

9 198. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
10 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
11 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
12 that spending had tripled to \$288 million.

13 **E. All Defendants Created an Illicit Market for Opioids**

14 199. In addition to the allegations above, all Defendants played a role in the creation of
15 an illicit market for prescription opioids, further fueling the opioid epidemic.

16 200. Defendants' distribution of opioids was driven by national policies, coordination,
17 plans, and procedures that were the same in California as they were across the rest of the United
18 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
19 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
20 vastly increasing their respective profits and revenues by exponentially expanding a market that the
21 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
22 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
23 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
24 possible financial return.

25 201. Each participant in the supply chain shares the responsibility for controlling the
26 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of
27 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
28 distribution or use to an illegitimate channel of distribution or use.

1 202. Diversion can occur at any point in the opioid supply chain.

2 203. For example, diversion can occur at the wholesale level of distribution when
3 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
4 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
5 size, orders that are disproportionately large in comparison to the population of a community served
6 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

7 204. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
8 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
9 usual course of practice. Some of the signs that a prescription may have been issued for an
10 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
11 different doctors (known as doctor shopping), when they travel great distances between the doctor
12 or their residence and the pharmacy to get the prescription filled, when they present multiple
13 prescriptions for the largest dose of more than one controlled substance, or when there are other
14 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
15 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
16 to treat a legitimate medical condition.

17 205. Diversion occurs through the use of stolen or forged prescriptions or the sale of
18 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
19 Opioids can also be diverted when stolen by employees or others.

20 206. Opioid diversion occurs at an alarming rate in the United States.

21 207. Each participant in the supply chain, including each Defendant, has a common law
22 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
23 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
24 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
25 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

26 208. Defendants, and not Plaintiff, controlled the manufacture, marketing, and
27 distribution of prescription opioids within Plaintiff’s boundaries. As such, Defendants were in the
28 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.

1 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

2 209. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
3 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
4 duty in their misleading and inaccurate promotion of prescription opioids.

5 210. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
6 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
7 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
8 suspicious orders.

9 **211.** In addition to their common law duties, Defendants possess duties under California
10 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
11 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
12 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
13 4164 and 4169.1.

14 212. Separately, Defendants also are subject to federal statutory requirements of the
15 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
16 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
17 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
18 U.S.C.C.A.N. 4566, 4572.

19 213. Defendants' repeated and prolific violations of these requirements show that they
20 have failed to meet the relevant standard of conduct that society expects of them: the duty to
21 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
22 willful disregard for Kern County and the people therein.

23 214. California law requires Defendants to report suspicious orders of dangerous drugs
24 subject to abuse, and to develop and maintain systems to detect and report such activity. This
25 framework acts as a system of checks and balances from the manufacturing level through delivery
26 of the controlled substance to the patient or ultimate user.

27 215. Thus, all opioid distributors are required to maintain effective controls against
28 opioid diversion. They are required to create and use a system to identify and report to the California

1 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
2 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
3 and/or orders of unusual frequency. To comply with these requirements, distributors must know
4 their customers, must conduct due diligence, must report suspicious orders, and must terminate
5 orders if there are indications of diversion.

6 216. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
7 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
8 their obligations under the CSA.

9 217. Under the CSA, anyone authorized to handle controlled substances must track
10 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
11 automated drug reporting system that records and monitors the flow of Schedule II controlled
12 substances from the point of manufacture through distribution to the point of sale. ARCOS
13 accumulates data on distributors' controlled substances and transactions, which are then used to
14 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
15 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
16 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
17 and current record of each substance manufactured, imported, received, sold, delivered, exported,
18 or otherwise disposed of.

19 218. Plaintiff does not bring causes of action based on violations of federal statutes and
20 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
21 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
22 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
23 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
24 prescription opioids.

25 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
26 **Opioids to Kern County Through Illicit Channels**

27 219. The Distributor Defendants have been and continue to be well-aware of problems
28 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance

1 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
2 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
3 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
4 that the DEA also provides distributors with data on controlled substance distribution patterns and
5 trends, including data on the volume and frequency of orders and the percentage of controlled
6 versus non-controlled purchases. The distributors are also given case studies, legal findings against
7 other registrants, and ARCOS profiles of their customers whose previous purchases may have
8 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
9 Defendants should look for in order to identify potential diversion.

10 220. Since 2007, the DEA has hosted at least five conferences to provide registrants with
11 updated information about diversion trends and regulatory changes that affect the drug supply
12 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
13 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
14 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
15 also request clarification on DEA policies, procedures, and interpretations of the CSA and
16 implementing regulations.

17 221. Since 2008, the DEA also has participated in numerous meetings and events with
18 the legacy Healthcare Distribution Management Association (HDMA), now known as the
19 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
20 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
21 guidance to the association concerning suspicious order monitoring, and the association has
22 published guidance documents for its members on suspicious order monitoring, reporting
23 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
24 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”
25 (2008).)

26 222. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
27 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
28 and the responsibilities and obligations of registrants to prevent diversion.

1 223. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
2 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
3 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
4 orders must be reported when discovered and monthly transaction reports of excessive purchases
5 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
6 that they must perform an independent analysis of a suspicious order prior to the sale to determine
7 if controlled substances would likely be diverted, and that filing a suspicious order and then
8 completing the sale does not absolve the registrant from legal responsibility.

9 224. Distributor Defendants' own industry group, the Healthcare Distribution
10 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
11 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
12 member of the supply chain in distributing controlled substances. These industry guidelines stated:
13 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
14 diligence in order to help support the security of controlled substances they deliver to their
15 customers."

16 225. Opioid distributors have admitted to the magnitude of the problem and, at least
17 superficially, their legal responsibility to prevent diversion. They have made statements assuring
18 the public they supposedly are undertaking a duty to curb the opioid epidemic.

19 226. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
20 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
21 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

22 227. McKesson has publicly stated that it has a "best-in-class controlled substance
23 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
24 curbing the opioid epidemic in our country."

25 228. On their face, these assurances that they would identify and eliminate criminal
26 activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take
27 reasonable measures to do just that.

28 229. Despite their duties to prevent diversion, the Distributor Defendants have knowingly

1 or negligently allowed diversion.⁵³

2 230. Their misconduct and negligent failure to prevent diversion is demonstrated by the
3 fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178
4 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of
5 Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The
6 Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and
7 other penalties, including:

- 8 a. In a 2017 Administrative Memorandum of Agreement between McKesson and
9 the DEA, McKesson admitted that it "did not identify or report to [the] DEA
10 certain orders placed by certain pharmacies which should have been detected
11 by McKesson as suspicious based on the guidance contained in the DEA
12 Letters." McKesson was fined \$150,000,000;⁵⁵
- 13 b. McKesson has a history of repeatedly failing to perform its duties. In May
14 2008, McKesson entered into a settlement with the DEA on claims that
15 McKesson failed to maintain effective controls against diversion of controlled
16 substances. McKesson allegedly failed to report suspicious orders from rogue
17 Internet pharmacies around the country, resulting in millions of doses of
18 controlled substances being diverted. McKesson's system for detecting
19 "suspicious orders" from pharmacies was so ineffective and dysfunctional that
20 at one of its facilities in Colorado between 2008 and 2013, it filled more than
21 1.6 million orders, for tens of millions of controlled substances, but it reported
22 just 16 orders as suspicious, all from a single consumer;
- 23 c. On November 28, 2007, the DEA issued an Order to Show Cause and
24 Immediate Suspension Order against a Cardinal Health facility in Auburn,
25 Washington, for failure to maintain effective controls against diversion;
- 26 d. On December 5, 2007, the DEA issued an Order to Show Cause and
27 Immediate Suspension Order against a Cardinal Health facility in Lakeland,
28 Florida, for failure to maintain effective controls against diversion;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

231. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

232. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 diversion created an enormous black market for prescription opioids, which market extended to
2 Kern County and its residents. Each Distributor Defendant knew or should have known that the
3 opioids reaching Kern County were not being consumed for medical purposes and that the amount
4 of opioids flowing to Kern County was far in excess of what could be consumed for medically
5 necessary purposes.

6 233. The Distributor Defendants negligently or intentionally failed to adequately control
7 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
8 substances would have anticipated the danger of opioid diversion and protected against it by, for
9 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
10 greater oversight, security, and control of supply channels; (c) looking more closely at the
11 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
12 amounts greater than the populations in those areas would warrant; (d) investigating demographic
13 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
14 Kern County; (e) providing information to pharmacies and retailers about opioid diversion; and (f)
15 in general, simply following applicable statutes, regulations, professional standards, and guidance
16 from government agencies and using a little bit of common sense.

17 234. On information and belief, the Distributor Defendants made little to no effort to visit
18 the pharmacies servicing the areas around Kern County to perform due diligence inspections to
19 ensure that the controlled substances the Distributor Defendants had furnished were not being
20 diverted to illegal uses.

21 235. On information and belief, the compensation the Distributor Defendants provided
22 to certain of their employees was affected, in part, by the volume of their sales of opioids to
23 pharmacies and other facilities servicing the areas around Kern County, thus improperly creating
24 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid
25 abuse.

26 236. It was reasonably foreseeable to the Distributor Defendants that their conduct in
27 flooding the market in and around Kern County with highly addictive opioids would allow opioids
28 to fall into the hands of children, addicts, criminals, and other unintended users.

1 237. It was reasonably foreseeable to the Distributor Defendants that, when unintended
2 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
3 and death. It was also reasonably foreseeable that many of these injuries would be suffered by Kern
4 County residents, and that the costs of these injuries would be borne by Kern County.

5 238. The Distributor Defendants knew or should have known that the opioids being
6 diverted from their supply chains would contribute to the opioid epidemic faced by Kern County,
7 and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
8 addiction, demand, illegal transactions, economic ruin, and human tragedy.

9 239. The Distributor Defendants were aware of widespread prescription opioid abuse in
10 and around Kern County, but, on information and belief, they nevertheless persisted in a pattern of
11 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
12 with such frequency that they knew or should have known these commonly abused controlled
13 substances were not being prescribed and consumed for legitimate medical purposes.

14 240. The use of opioids by Kern County residents who were addicted or who did not have
15 a medically necessary purpose could not have occurred without the knowing cooperation,
16 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
17 Defendants adhered to effective controls to guard against diversion, Kern County and its residents
18 would have avoided significant injury.

19 241. The Distributor Defendants made substantial profits over the years based on the
20 diversion of opioids into Kern County. The Distributor Defendants knew that Kern County would
21 be unjustly forced to bear the costs of these injuries and damages.

22 242. The Distributor Defendants' intentional distribution of excessive amounts of
23 prescription opioids showed an intentional or reckless disregard for the safety of Kern County and
24 its residents. Their conduct poses a continuing threat to the health, safety, and welfare of Kern
25 County.

26 243. The state laws at issue here are public safety laws.

27 244. The Distributor Defendants' violations constitute prima facie evidence of
28 negligence under state law.

2. The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Kern County Through Illicit Channels

245. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under California law.

246. In addition to a common law duty to exercise reasonable care in the promotion and marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts determined by the Board. *See* 16 CCR 1782.

247. On information and belief, for over a decade the Manufacturer Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Manufacturer Defendants breached their duties under state law.

248. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

249. The Manufacturer Defendants’ actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful

1 diversion of opioids into Kern County.

2 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

3 250. As the demand for prescription opioids grew, fueled by their potency and purity,
4 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
5 traveling across state, city, and county lines in a variety of ways.

6 251. First, prescriptions written in one state would, under some circumstances, be filled
7 in a different state. But even more significantly, individuals transported opioids from one
8 jurisdiction specifically to sell them in another.

9 252. When authorities in one state cracked down on opioid suppliers, out-of-state
10 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
11 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
12 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
13 practice became so common that authorities dubbed these individuals “prescription tourists.”

14 253. The facts surrounding numerous criminal prosecutions illustrate this common
15 practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught
16 flying to California in attempts to obtain additional sources of supply for their drug operation which
17 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

18 254. In another example, a man from Warren County, Ohio, who was sentenced to four
19 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
20 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
21 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a
22 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
23 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader

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25 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

26 ⁵⁹ Andrew Welsh-Huggins, Associated Press, ‘*Prescription Tourists’ Thwart States’ Crackdown on Illegal Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

27 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
28 <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last accessed July 25, 2018).

1 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
2 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
3 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
4 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

5 255. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
6 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
7 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
8 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
9 customers were from other states.⁶³

10 256. In yet another case, defendants who operated a pill mill in south Florida within
11 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
12 transported oxycodone back to the area for both use and distribution by local drug trafficking
13 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
14 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
15 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
16 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
17 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
18 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
19 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
20 Kentucky residents.”⁶⁵

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22 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
23 available at http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html (last accessed July 25, 2018).

24 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
25 <https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last accessed July 25, 2018).

26 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
27 <https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill> (last accessed July 25, 2018).

28 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

⁶⁵ *Id.* at 861.

257. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

258. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.⁷⁰

259. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.

260. Along the west coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²

⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America's Deadliest Drug Epidemic* 171 (2016).

⁶⁷ *Id.* at 172

⁶⁸ *Id.* at 171

⁶⁹ *Id.*

⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71> (last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*, Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running> (last accessed July 25, 2018)

⁷² Harriet Ryan et al., *How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and*

1 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
 2 Everett-based dealer who received the pills from southern California wore a diamond necklace in
 3 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
 4 OxyContin—connecting Los Angeles and Washington state.

5 261. Defendants certainly were aware, or should have been aware, that pill mills from
 6 around the country were pushing its products. Defendants purchased nationwide, regional, state,
 7 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
 8 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
 9 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
 10 compute, and track their competitors' sales, and to compare and analyze market share information.

11 262. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
 12 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
 13 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
 14 regarding competing drugs, and analyzed the market share of those drugs.

15 263. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
 16 rewarded sales representatives who happened to have pill mills within their territories, enticing
 17 those representatives to look the other way even when their in-person visits to such clinics should
 18 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
 19 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
 20 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
 21 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric
 22 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
 23 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
 24 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
 25 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
 26

27 _____
 28 Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

⁷³ *Id.*

1 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

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3 264. In another example, a Purdue sales manager informed her supervisors in 2009 about
4 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
5 sales representative “it was packed with a line out the door, with people who looked like gang
6 members,” and that she felt “very certain that this an organized drug ring[.]”⁷⁵ She wrote, “This is
7 clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue
8 responded that while they were “considering all angles,” it was “really up to [the wholesaler] to
9 make the report.”⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
10 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
11 2010 to inform the authorities.

12 265. Abundant evidence, thus, establishes that prescription opioids migrated between
13 states, counties, and cities and that Defendants were aware of it. As a result, Defendants’ public
14 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
15 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
16 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
17 prescription opioid pills were hard to get in one area, they migrated from another. The
18 manufacturers and distributors were fully aware of this phenomenon and profited from it.

19 266. Defendants each knew or should have known that opioid diversion and abuse was
20 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide
21 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
22 allowed to continue the unlawful diversion of opioids into Kern County.

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26 ⁷⁴ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages

267. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and the sale of their products, as well as the rates of opioid-related substance abuse, hospitalization, and death among Kern County residents and across the nation. Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of opioids into communities like Kern County, fueling the epidemic.

268. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."⁷⁷

269. Opioids are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

270. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."⁷⁹

271. The increased abuse of prescription opioids—along with growing sales—has contributed to a large number of overdoses and deaths.

272. As shown above, the opioid epidemic has escalated in Kern County with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants' increased distribution of opioids.

273. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to Kern County and areas from which opioids are being diverted to Kern County, has caused the opioid epidemic to include heroin addiction, abuse, and death.

274. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Kern County.

⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

275. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Kern County.

276. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in Kern County.

277. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in Kern County. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by Kern County and residents of Kern County.

278. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Kern County seeks relief, as alleged herein. Kern County also seeks the means to abate the epidemic created by the Defendants.

279. Kern County seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

280. Kern County seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

281. Kern County seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

282. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

283. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

284. The community-based problems require community-based solutions that have been

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed January 8, 2018).

1 limited by budgetary constraints.

2 285. Having profited enormously through the aggressive sale, misleading promotion, and
3 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
4 financial burdens their conduct has inflicted upon Kern County.

5 286. The opioid epidemic still rages because the fines and suspensions imposed by the
6 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
7 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
8 registration numbers and when one facility is suspended, they simply ship from another facility.

9 287. The Defendants have abandoned their duties imposed by the law, taken advantage
10 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
11 Kern County.

12 288. In the course of conduct described in this Complaint, Defendants have acted with
13 oppression, fraud, and malice, both actual and presumed.

14 **H. The Impact of Opioid Abuse on Kern County**

15 289. Defendants' creation, through false and misleading advertising and a failure to
16 prevent diversion, of a virtually limitless opioid market has significantly harmed Kern County and
17 resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
18 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
19 abused come, directly or indirectly, through doctors' prescriptions.

20 290. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
21 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
22 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
23 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
24 associated with the consumption of a counterfeit version of the prescription drug Norco
25 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has
26 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
27 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
28 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further

1 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
2 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
3 concern.

4 291. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
5 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
6 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
7 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
8 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

9 292. Even Kern County's youngest residents bear the consequences of the opioid abuse
10 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
11 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
12 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
13 Many Kern County women have become addicted to prescription opioids and have used these drugs
14 during their pregnancies. As a result, many Kern County infants suffer from opioid withdrawal and
15 Neonatal Abstinence Syndrome ("NAS").⁸⁵

16 293. The impact of NAS can be life-long. Most NAS infants are immediately transferred
17 to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require
18 an emergency evacuation for care to save the infant's life. Such emergency transportation can cost
19 thousands of dollars for each occurrence.
20

21 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
22 *year*, LA Times (Oct. 27, 2014), available at <http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html> (last accessed December 21, 2017).

23 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
24 *The Opioid Crisis in Indian Country*, at 37, available at
<https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
25 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US., 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

26 ⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
27 Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
28 21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at
<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 294. Many NAS infants have short-term and long-term developmental issues that prevent
2 them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and
3 digestive issues; some are unable to attend full days of school. These disabilities follow these
4 children through elementary school and beyond.

5 295. Many of the parents of these children continue to relapse into prescription opioid
6 use and abuse. As a result, many of these children are placed in foster care or adopted.

7 296. Opioid addiction is now the primary reason that Californians seek substance abuse
8 treatment, and admissions to drug treatment facilities in California more than doubled from
9 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one
10 facility in northern California, up to 90% – started on legal opioid prescriptions.

11 297. The explosion in opioid prescriptions and use caused by Defendants has led to a
12 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
13 overdoses and deaths as well as devastating social and economic consequences. This public health
14 crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable
15 enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]”
16 and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each
17 Defendant’s deceptive marketing and distribution scheme are catastrophic and are only getting
18 worse.

19 298. There is little doubt that each Defendant’s deceptive marketing and distribution
20 scheme has precipitated this public health crisis in California, including Kern County, by
21 dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has
22 provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids
23 has created a population of patients physically and psychologically dependent on them (the
24 demand). And when those patients can no longer afford or legitimately obtain opioids, they often
25 turn to the street to buy prescription opioids or even heroin.

26 299. The effects of Defendants’ deceptive marketing and distribution scheme has further
27 impacted Plaintiff in a foreseeable way such that Kern County must devote increased resources to
28 the burden of the addicted homeless who commit drug and property crimes, to feed their addiction.

1 For example, tax dollars are required to maintain public safety of places where the addicted
 2 homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required
 3 to fight the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
 4 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
 5 *aureus* (MRSA) are spread by opioid abuse.

6 300. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
 7 have recruited addicts nationally with false and misleading promises of the medically supervised
 8 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
 9 effective rehabilitation available in beautiful California communities. These for-profit
 10 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
 11 that many have provided substandard care including use of physicians who have had their license
 12 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
 13 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
 14 as long as there are third party payments available, and then throw them out of the facilities to be
 15 homeless. These addicts brought to California by the substandard rehab industry, have further
 16 contributed to the public's burden by discharging addicted homeless into the community who
 17 require further care and rehabilitation at the public's expense, and who commit crimes in California
 18 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
 19 all relevant times when they deceptively marketed their products as non-addictive that such
 20 addiction would be highly difficult to overcome. Defendants knew or should have known that
 21 municipalities, including Kern County, would bear the burden of costs associated with
 22 rehabilitation business of all types.

23 301. The role of Defendants' deceptive marketing and distribution scheme in causing this
 24 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
 25 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
 26 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have
 27 contributed to the severity of the current prescription drug abuse problem." And in August 2016,
 28 the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy

1 marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that opioids
2 are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment
3 specialists, and law enforcement and public health officials confirm that prescription opioids
4 lawfully prescribed by doctors have fueled this epidemic.

5 302. Absent each Defendant’s deceptive marketing scheme and improper distribution,
6 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
7 the opioid epidemic that now exists would have been averted or much less severe.

8 303. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
9 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
10 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
11 only engaged in false advertising, they have also created or assisted in the creation of a public
12 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the
13 present is part of its deceptive marketing and distribution scheme and subjects that Defendant to
14 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
15 *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual
16 obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance
17 of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

18 304. Accordingly, Defendants’ conduct, both individually and collectively, has violated
19 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
20 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Kern County does not seek to limit
21 the ability of doctors in California to prescribe opioids. Kern County does not ask this Court to
22 weigh the risks and benefits of long-term opioid use. Instead, Kern County seeks an order requiring
23 Defendants to cease their unlawful promotion and distribution of opioids, to correct their
24 misrepresentations, and to abate the public nuisance they have created. To redress and punish
25 Defendants’ previous and current violations of law that cause and continue to cause harm to Kern
26 County, Plaintiff seeks a judgment requiring Defendants to pay civil penalties, and any fees or costs
27 permitted under law.

28 305. By this action, Kern County further seeks to recoup tax dollars spent already for the

1 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
2 impact on this county and its communities, and to abate the opioid nuisance so Kern County will
3 not be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
4 wrongful conduct as alleged herein.

5 306. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
6 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
7 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
8 California spiked by 34% from 2011 to 2013.

9 307. Opioid abuse also contributes to a range of social problems including physical and
10 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
11 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
12 unemployment, and despair. More and more Kern County resources are needed to combat these
13 problems. Kern County faces a growing employment staffing problem, as critical services such as
14 social services and victims' assistance programs have experienced high rates of employee turnover
15 due to the opioid-related nature of the work. The prescription opioid crisis also diminishes Kern
16 County's available workforce, decreases productivity, increases poverty, and requires greater
17 governmental expenditures by Kern County.

18 308. The prescription opioid crisis has directly financially injured Kern County. The
19 crisis has led to an increased demand for, *inter alia*, security services (such as police, EMS,
20 detention), child protective services, health services, clean-up services, and legal services. Kern
21 County has also had to hire additional staff and expend additional resources to manage the demand.

22 309. Kern County's medical services have seen an increase in opioid-related health
23 problems among Kern County residents, including, but not limited to, infants born with opioid-
24 related medical conditions. This has resulted in increased demand, difficulty retaining staff, and
25 increased expenses.

26 310. Kern County has also suffered substantial financial damages in the form of lost
27 productivity of Kern County employees and residents, lost economic activity, lost reputation and
28 good will, and the lost opportunity for growth. These damages have been suffered and continue to

1 be suffered directly by Kern County.

2 311. Many patients who become addicted to opioids will lose their jobs. Some will lose
3 their homes and their families. Some will get treatment and fewer will successfully complete it;
4 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
5 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
6 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
7 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
8 drug transactions; or dying from opioid-induced heart or neurological disease.

9 312. Kern County also has suffered substantial financial damages in the form of lost taxes
10 paid by its residents and businesses as a result of lost earnings and productivity.

11 313. While the use of opioids has taken an enormous toll on Kern County and its
12 residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11
13 billion in revenue for drug companies like the Defendants. Indeed, on information and belief, each
14 Defendant experienced a material increase in sales, revenue, and profits from the unlawful conduct
15 described above.

16 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
17 **Asserting Statutes of Limitations As Defenses**

18 314. Defendants' conduct has continued from the early 1990s through today and remains
19 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
20 continuous injury. The damages have not occurred all at once but have continued to occur and have
21 increased as time progresses. The tort is not completed nor have all the damages been incurred until
22 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
23 public nuisance remains unabated.

24 315. Defendants are equitably estopped from relying upon a statute of limitations defense
25 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
26 assure the public that they were undertaking efforts to comply with their obligations under the
27 controlled substances laws, all with the goal of continuing to generate profits.

28 316. For example, a Cardinal Health executive claimed that it uses "advanced analytics"

1 to monitor its supply chain, and assured the public it was being “as effective and efficient as
2 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

3 317. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
4 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
5 curbing the opioid epidemic in our country.”⁸⁷

6 318. Defendants, through their trade associations, filed an amicus brief that represented
7 that Defendants took their duties seriously, complied with their statutory and regulatory
8 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

9 319. Defendants purposely concealed their wrongful conduct, including by assuring the
10 public and governmental authorities that they were complying with their obligations and were
11 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
12 behavior by providing the public with false information about opioids and have continued to use
13 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
14 is continuing to this day.

15 320. Defendants have also concealed and prevented discovery of information, including
16 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
17 and illegal activities.

18 321. Defendants also lobbied Congress and actively attempted to halt DEA investigations
19 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
20 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a

21
22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
[https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
24 [of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
25 [7b6c1998b7a0_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html) (last accessed December 21, 2017)

26 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
27 *Opioid Abuse*, Wash. Post, (Dec. 22, 2016), available at
28 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html)
[industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html) (last accessed December 21,
2017).

⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

⁸⁹ See Higham and Bernstein, *supra* note 53.

1 distributor's license was raised.

2 322. In addition, the Defendants fraudulently attempted to convince the public that they
3 were complying with their legal obligations and working to curb the opioid epidemic.

4 323. Because the Defendants concealed the facts surrounding the opioid epidemic, Kern
5 County did not know if the existence or scope of the Defendants' misconduct, and could not have
6 acquired such knowledge earlier through the exercise of reasonable diligence.

7 324. Defendants intended that their false statements and omissions be relied upon,
8 including by Kern County, and its residents.

9 325. Defendants knew of their wrongful acts and had material information pertinent to
10 their discovery, but concealed that information from the public, including Kern County, and its
11 residents. Only Defendants knew of their widespread misinformation campaign and of their
12 repeated, intentional failures to prevent opioid diversion.

13 326. Defendants cannot claim prejudice due to a late filing because this suit was filed
14 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
15 opioid crisis have only recently come to light.

16 327. Defendants had actual knowledge that their conduct was deceptive, and they
17 intended it to be deceptive.

18 328. Kern County was unable to obtain vital information regarding these claims absent
19 any fault or lack of diligence on Kern County's part.

20 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

21 **A. The Marketing Scheme**

22 329. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
23 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
24 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
25 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
26 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
27 long-term, chronic pain. Through their personal relationships, the members of this marketing
28 scheme had the opportunity to form and take actions in furtherance of their common purpose. The

1 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
2 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

3 330. The Manufacturer Defendants, through their marketing scheme, concealed the true
4 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
5 made misleading statements and misrepresentations about opioids that downplayed the risk of
6 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
7 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
8 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
9 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
10 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
11 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
12 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
13 formulations provide a solution to opioid abuse.

14 331. The marketing scheme devised, implemented and conducted by the Manufacturer
15 Defendants was designed to ensure that they unlawfully increased their sales and profits through
16 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
17 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
18 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
19 network as described above.

20 332. There was regular communication between the Manufacturer Defendants, Front
21 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
22 exchanged. Typically, the coordination, communication and payment occurred, and continues to
23 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
24 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
25 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
26 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
27 each agreed and took actions to hide the scheme and continue its existence.

28 333. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'

1 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
 2 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
 3 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
 4 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
 5 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
 6 their members and constituents. By failing to disclose this information, Front Groups perpetuated
 7 the marketing scheme, and reaped substantial benefits.

8 334. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
 9 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
 10 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
 11 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
 12 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
 13 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
 14 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
 15 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
 16 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
 17 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
 18 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
 19 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

20 335. As public scrutiny and media coverage focused on how opioids ravaged
 21 communities in California and throughout the United States, the Front Groups and KOLS did not
 22 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
 23 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
 24 using opioids for chronic pain.

25 336. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
 26 categories of activities in furtherance of the marketing scheme. As described herein, the
 27 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
 28 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe

1 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
2 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
3 and (d) efforts to limit prescriber accountability.

4 337. In addition to disseminating misrepresentations about the risks and benefits of
5 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
6 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
7 criticized or undermined the CDC Guidelines which represented “an important step – and perhaps
8 the first major step from the federal government - toward limiting opioid prescriptions for chronic
9 pain.”

10 338. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
11 the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not
12 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
13 of the individuals who participated in the construction of these guidelines.”

14 339. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
15 president, stating “that the CDC guideline makes disproportionately strong recommendations based
16 upon a narrowly selected portion of the available clinical evidence.”

17 340. The Manufacturer Defendants alone could not have accomplished the purpose of the
18 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
19 “neutral” and more “scientific” than the Manufacturer Defendants themselves. Without the work
20 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
21 scheme could not have achieved its common purpose.

22 341. The impact of the marketing scheme remains in place—i.e., the opioids continue to
23 be prescribed and used for chronic pain throughout Kern County, and the epidemic continues to
24 injure Plaintiff, and consume the resources of Plaintiff’s health care and law enforcement systems.

25 342. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
26 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
27 in the object of the scheme, and functioned within a structure designed to effectuate the scheme’s
28 purpose.

B. The Distribution Scheme

343. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to “a categorical denial of any criminal behavior or intent.”⁹⁰ Defendants’ actions went far beyond what could be considered ordinary business conduct. For more than a decade, the Distributor Defendants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

344. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, California enacted California Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems to detect and report such activity.

345. If morality and the law did not suffice, competition dictates that the Distributor Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so.

346. The Distributor Defendants’ scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for state authorities or the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the

⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, the Distributor Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

347. As described above, at all relevant times, the Distributor Defendants conspired together for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

348. At all relevant times, as described above, the Distributor Defendants exerted control over, conducted and/or participated in distribution scheme by fraudulently claiming that they were complying with their duties under California law to report suspicious orders and to maintain systems to detect and report such activity.

349. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators’ ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁹¹

⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at <https://www.w>

350. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

351. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

352. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

353. Each Defendant's conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under California Business & Professions Code § 17536.

354. As a members of the boards of various Purdue entities, the Sacklers oversaw all

[washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html) (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 aspects of Purdue's marketing and promotion of opioid products. As board members who were
2 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
3 known, of Purdue's deceptive marketing tactics of opioid products.

4 355. The Sackler Defendants also were aware of specific examples of deceptive
5 marketing through receipt of call note reviews in their capacities as board members. On information
6 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
7 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
8 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

9 356. The Sackler Defendants were personally aware that: (1) OxyContin was being
10 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
11 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
12 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

13 357. By 2006, prosecutors at the United States Department of Justice found damning
14 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
15 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
16 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
17 events and side effects than other pain medications.

18 358. As members of the family that owns Purdue, the Sackler Defendants personally
19 benefitted from the success of OxyContin. At various points, as directors, they approved the
20 distribution of funds from Purdue to shareholders, including themselves and their extended family.

21 359. Since at least 1999, the Sackler Defendants were aware of potential liability for
22 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
23 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
24 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
25 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
26 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
27 the opioid related liabilities of the companies from which they were transferred.

28 360. Plaintiff is informed and believes that due to the billions of dollars in profits that

1 have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to
 2 satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced
 3 litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the
 4 Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly
 5 profited and received the benefits of that wrongdoing.

6 VII. CAUSES OF ACTION

7 FIRST CAUSE OF ACTION

8 (Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)

9 361. Plaintiff realleges and incorporates herein by reference each and every allegation in
 10 paragraphs 1 through 359 above as if set forth fully herein.

11 362. California Civil Code § 3479 provides that “anything which is injurious to health ...
 12 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
 13 interfere with the comfortable enjoyment of life or property ... is a nuisance.”

14 363. California Civil Code § 3480 defines a “public nuisance” as “one which affects at
 15 the same time an entire community or neighborhood, or any considerable number of persons,
 16 although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

17 364. California Civil Code § 3490 states that “no lapse of time can legalize a public
 18 nuisance, amounting to an actual obstruction of public right.”

19 365. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought
 20 by Kern County to abate the public nuisance created by the Defendants.

21 366. Each Defendant, acting individually and in concert, has created or assisted in the
 22 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment
 23 of life and property of entire communities or neighborhoods or of any considerable number of
 24 persons in Kern County in violation of California Civil Code §§ 3479 and 3480.

25 367. The public nuisance is substantial and unreasonable. Defendants’ actions caused and
 26 continue to cause the public health epidemic described above in Kern County, and that harm
 27 outweighs any offsetting benefit.

28 368. Defendants knew and should have known that their promotion and distribution of

1 opioids was false and misleading and that their deceptive marketing scheme would create or assist
2 in the creation of the public nuisance—i.e., the opioid epidemic.

3 369. Defendants' actions were, at the very least, a substantial factor in opioids becoming
4 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
5 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
6 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
7 so widespread, and the opioid epidemic that now exists would have been averted or much less
8 severe.

9 370. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
10 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
11 can be abated.

12 371. Each Defendant is liable for public nuisance because its conduct at issue is
13 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
14 endangers the safety, health, morals, comfort, or repose of a considerable number of people in Kern
15 County. Defendants' conduct is also indecent or offensive to the senses, and constitutes an
16 obstruction to the free use of property sufficient to constitute an interference with the people of
17 Kern County's comfortable enjoyment of life or property.

18 372. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
19 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
20 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
21 unreasonable interference with Kern County and its residents' public rights, including, but not
22 limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to
23 be free from disturbance and reasonable apprehension of danger to person or property.

24 373. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
25 interfered with Kern County and its residents' public rights by, *inter alia*, engaging in a promotion
26 and marketing scheme that pushed the use of opioids for indications not federally approved, and by
27 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
28 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer

1 Defendants failed to comply with federal law.

2 374. Defendants have also unlawfully and intentionally distributed opioids or caused
3 opioids to be distributed within and without Kern County absent effective controls against
4 diversion. Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures
5 to maintain effective controls against diversion include Defendants' failure to effectively monitor
6 for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

7 375. Defendant's unreasonable interference with Kern County residents' public rights
8 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
9 expenditures to combat and address these harms. Kern County has also made payments for opioid
10 addiction treatment. These damages have been suffered and continue to be suffered directly by
11 Kern County and its residents.

12 376. Defendants' actions have also created a palpable climate of fear, distress,
13 dysfunction and chaos among residents of Kern County where opioid diversion, abuse, and
14 addiction are prevalent and where diverted opioids are used frequently. Specifically, Defendants
15 conduct has caused, among other things, (a) routine separation of children from parents who have
16 fallen victim to easy access to opioids and/or related crime; (b) children to have easy access and to
17 become addicted to opioids; (c) residents to endure both the emotional and financial costs of caring
18 for loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public
19 spaces and property; (e) property crimes throughout Kern County; (f) employers to lose the value
20 of productive and healthy employees; (g) increased public health and safety costs; (h) a decrease in
21 property values within Kern County; and (g) a decrease in tax revenues for Kern County.

22 377. The impact of Defendants' conduct on Kern County is of a continuing nature.
23 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

24 378. Defendants knew or should have known that their actions would lead to the national
25 opioid epidemic and to the resulting injuries to the public rights of Kern County.

26 379. Kern County has sustained a special and peculiar injury because its damages
27 include, *inter alia*, health service expenditures, public safety expenditures, payment of opioid
28 addiction treatment, decreased tax revenues and property values, and other costs related to opioid

addiction treatment and overdose prevention.

380. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

381. Defendants' actions are a direct and proximate contributing cause of the opioid epidemic and the injuries to the public rights of Kern County and its residents.

382. Defendants, individually and collectively, are at the very least, a substantial factor in causing the national opioid epidemic and of the injuries to Kern County and its residents.

383. The injuries to the public rights of Kern County and its residents are indivisible injuries.

384. Defendants' manufacture, marketing, distribution, and sale of prescription opioids, if unabated, will continue to cause an unreasonable interference with public rights of Kern County and its residents.

385. Defendants' conduct is ongoing and persistent, and Kern County seeks all damages flowing from Defendants' conduct. Kern County seeks economic losses (direct, incidental, and/or consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described above. Kern County does not seek damages for the wrongful death, physical personal injury, or emotional distress caused by Defendants' actions.

386. Pursuant to Code of Civil Procedure § 731, Kern County requests an order providing for abatement of the public nuisance that Defendants created or assisted in the creation of, and enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

SECOND CAUSE OF ACTION
(Fraud – Against All Defendants)

387. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 385 above as if set forth fully herein.

388. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth herein

389. The Defendants made fraudulent misrepresentations and omissions of material fact. Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,

1 were intended to induce reliance.

2 390. Those misrepresentations and omissions were known to be untrue by the
3 Defendants, or were recklessly made.

4 391. As alleged herein, the Manufacturer Defendants engaged in false representations
5 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
6 dangers of abuse, and the risks of addiction.

7 392. As alleged herein, Defendants made false statements and/or omissions regarding
8 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
9 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
10 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
11 opioids, within Kern County.

12 393. Defendants made those misrepresentations and omissions in an intentional effort to
13 deceive Kern County and its residents, despite the Defendants' knowledge of the dangers of such
14 use of prescription opioids.

15 394. In addition and independently, Defendants had a duty not to deceive Plaintiff
16 because Defendants had in their possession unique material knowledge that was unknown, and not
17 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

18 395. The Defendants continued making those misrepresentations, and failed to correct
19 those material omissions, despite repeated regulatory settlements and publications demonstrating
20 the false and misleading nature of the Defendants' omissions and/or claims.

21 396. While Defendants had a duty to disclose the above-referenced material facts, they
22 nevertheless concealed them. These false representations and concealed facts were material to the
23 conduct and actions at issue. Defendants made these false representations and concealed facts with
24 knowledge of the falsity of their representations and did so with the intent of misleading Kern
25 County, its residents, the public, and persons on whom these entities relied.

26 397. Defendants intended and had reason to expect under the operative circumstances
27 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
28 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein

1 and that these entities would act or fail to act in reasonable reliance thereon.

2 398. Kern County, its residents, and others, did in fact rightfully, reasonably, and
3 justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

4 399. For instance, doctors, including those serving Kern County and its residents, relied
5 on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
6 Patients, including residents of Kern County, relied on the Defendants' misrepresentations and
7 omissions in taking prescription opioids for chronic pain relief.

8 400. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
9 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
10 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
11 effective response to the opioid crisis.

12 401. Defendants' misconduct alleged in this case is ongoing and persistent.

13 402. Kern County has experienced an unprecedented opioid addiction and overdose
14 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
15 services, and lost productivity to Kern County's workforce.

16 403. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
17 result of Defendants' fraudulent conduct.

18 404. As a direct and foreseeable consequence of Defendants' fraud, Kern County has
19 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
20 opioid addiction treatment and its secondary consequences in excess of those Kern County would
21 have otherwise incurred.

22 405. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
23 fraudulent, entitling Kern County to punitive damages.

24 **THIRD CAUSE OF ACTION**
25 **(Negligence – Against All Defendants)**

26 406. Plaintiff realleges and incorporates herein by reference each and every allegation in
27 paragraphs 1 through 404 above as if set forth fully herein.

28 407. To establish actionable negligence in California, Plaintiff must show a duty, a breach

1 of that duty, and injury resulting proximately therefrom.

2 408. Defendants have a duty to exercise reasonable care under the circumstances, in light
3 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
4 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
5 and still have, a duty to exercise reasonable care to prevent the threatened harm.

6 409. In addition, Defendants had a duty not to breach the standard of care established
7 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
8 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
9 to abuse, and to develop and maintain systems to detect and report such activity.

10 410. Defendants voluntarily undertook a legal duty to prevent the diversion of
11 prescription opioids by engaging in the distribution of prescription opioids and by making public
12 promises to prevent the diversion of prescription opioids.

13 411. Defendants knew of the serious problem posed by prescription opioid diversion and
14 were under a legal obligation to take reasonable steps to prevent diversion.

15 412. Defendants knew of the highly addictive nature of prescription opioids and of the
16 high likelihood of foreseeable harm to patients and communities, including Kern County, from
17 prescription opioid diversion.

18 413. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
19 in accordance with applicable standards of conduct in advertising, marketing, selling, and
20 distributing opioid products in a safe manner to minimize the risk of addiction in patients and
21 resultant harm to those patients, their families and their communities, and to taxpayers and
22 municipal government such as Kern County which must incur enormous expenditures for
23 prevention, treatment, emergency response and law enforcement costs and other foreseeable costs
24 related to the need to address the consequences of a large number of residents that become addicted
25 to opioids as a result of Defendants' conduct.

26 414. As described throughout the Complaint, Defendants breached their duties to
27 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
28 monitor for, failing to report, and filling highly suspicious orders time and again.

1 415. As described throughout the Complaint, in language expressly incorporated herein,
2 Defendants misrepresented their compliance with their duties under the law and concealed their
3 noncompliance and shipments of suspicious orders of opioids to Kern County and destinations from
4 which they knew opioids were likely to be diverted into Kern County, in addition to other
5 misrepresentations alleged and incorporated herein.

6 416. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
7 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
8 purported benefits of long-term use of opioids for the treatment of chronic pain.

9 417. Manufacturer Defendants knew or should have known, that their affirmative
10 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
11 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
12 representatives, and internal documents, should have put them on notice that such harm was not
13 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
14 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
15 and the public.

16 418. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
17 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

18 419. Defendants' misconduct alleged in this case is ongoing and persistent.

19 420. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
20 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
21 great probability of causing substantial harm.

22 421. As is described throughout this Complaint, Defendants acted without even slight
23 diligence or scant care, and with indifference, and were negligent in a very high degree,
24 disregarding the rights and safety of other persons, and said actions have a great probability of
25 causing substantial harm.

26 422. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
27 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
28 in the in advertising, marketing, selling and distributing opioid products in a safe manner to

1 minimize the risk of addiction in patients and resultant harm to those patients, their families and
 2 their communities, and to taxpayers and municipal government such as Kern County, including,
 3 but not limited to, the following:

- 4 a. Foreseeability of harm to Kern County: Defendants were aware or reasonably
 5 should have been aware of the risk of addiction of a large number of patients in
 6 places such as Kern County, and need for their care and treatment and in
 7 handling other consequences of their addiction and that such costs would be
 8 borne by local governments such as Kern County;
- 9 b. Degree of certainty Kern County suffered harm: Kern County has suffered
 10 enormous harm and costs in addressing treatment of addicted patients, including
 11 but not limited to expenditures for prevention, treatment, emergency response
 12 and law enforcement costs and other foreseeable costs related to the need to
 13 address the consequences of a large number of residents that become addicted
 14 to opioids as a result of Defendants' conduct;
- 15 c. Closeness of connection between Kern County's harm: The explosion of opioid
 16 addiction and the presence of opioid addicted patients in Kern County as a result
 17 of Defendants' conduct has resulted in expenditures directly for prevention,
 18 treatment, emergency response and law enforcement costs and other foreseeable
 19 costs related to the need to address the consequences;
- 20 d. Moral blame attached to Defendants' conduct: Defendants' knew or should have
 21 known that their wrongful conduct, actions and omissions would result in an
 22 explosion of patients who would become addicted to opioids, and that a vast
 23 opioid epidemic would result from the prescription of opioids to tens of millions
 24 of patients nationwide, including within Kern County, and that the costs would
 25
 26
 27
 28

1 be borne by the state, county and municipal local governments, while
2 Defendants profited tens of billions of dollars collectively from the widespread
3 use of prescription opioid products;

4
5 e. Policy of preventing future harm: As a direct and foreseeable result of
6 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
7 to occur on a vast scale both nationally and locally in places such as Kern County
8 resulting in tremendous harm and cost to the patients, their families and the
9 communities in dealing with this epidemic and crisis, and there is a need to
10 ensure that the costs of such wrongful conduct is borne by Defendants so that
11 parties contemplating such or similar conduct in the future know they will be
12 held responsible for such harm;

13
14 f. Extent of burden to Defendants: There is no burden to Defendants in that state
15 and other law precludes them from engaging in the conduct alleged herein, and
16 there is no burden from precluding Defendants from profiting from their
17 wrongful conduct and operating within the confines of the law in advertising,
18 marketing, selling and distributing opioid products in a safe manner to minimize
19 the risk of addiction in patients and resultant harm to those patients, their
20 families and their communities, and to taxpayers and municipal government
21 such as Plaintiff Kern County; and

22
23 g. Consequences to the community of imposing a duty to exercise care with
24 resulting liability for breach: Imposing a duty to not engage in Defendants'
25 wrongful conduct of advertising, marketing, selling and distributing opioid
26 products in an unsafe manner would minimize the risk of addiction in patients,
27 and liability for a breach of this duty would benefit communities such as Kern
28

County in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the country and the nation.

423. Plaintiff is not asserting a cause of action under the CSA or other federal controlled substances laws cited above.

424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for security services, emergency, health, prosecution, corrections, and rehabilitation services, as well as the cost of opioid addiction treatment paid by Kern County.

425. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

426. Defendants' breaches of their duty of care foreseeably and proximately caused damage to Kern County and its residents.

427. Manufacturer Defendants are guilty of negligence per se in that the Defendants violated applicable California laws, statutes, and regulations, in the manner in which they advertised, marketed, sold and distributed opioid products.

428. Distributor Defendants are guilty of negligence per se in that the Defendants violated California laws, statutes, and regulations designed to protect Plaintiff from the harms it has suffered, including, but not limited to, the following:

- a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110390;
- b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110395;
- c. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in

violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;

d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;

e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and

f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

429. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Kern County. Kern County, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

430. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Kern County to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

431. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

432. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and

1 purchase of opioids within Kern County, including from opioids foreseeably and deliberately
2 diverted within and into Kern County.

3 433. Plaintiff has expended substantial amounts of money in an effort to remedy or
4 mitigate the societal harms caused by Defendants' conduct.

5 434. These expenditures include, but are not limited to, the provision of healthcare
6 services and treatment services to people who use opioids. Plaintiff has also made payments for
7 opioid addiction treatment.

8 435. These expenditures have helped sustain Defendants' businesses.

9 436. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
10 externalities: the cost of the harms caused by Defendants' improper distribution practices.

11 437. Defendants were aware of these obvious benefits, and their retention of the benefit
12 is unjust.

13 438. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
14 benefited from those payments because they allowed them to continue providing customers with a
15 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
16 Defendants obtained enrichment they would not otherwise have obtained. Because of their
17 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
18 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
19 lacks a remedy provided by law.

20 439. Defendants' misconduct alleged in this case is ongoing and persistent.

21 440. Defendants have unjustly retained benefits to the detriment of Kern County, and
22 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
23 good conscience.

24 441. Kern County is entitled to restitution and disgorgement from Defendants in an
25 amount to be determined at trial.

26 **FIFTH CAUSE OF ACTION**
27 **(Civil Conspiracy – Against All Defendants)**

28 442. Plaintiff realleges and incorporates herein by reference each and every allegation in

1 paragraphs 1 through 440 above as if set forth fully herein.

2 443. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
3 and/or distribution of opioids into California and Kern County.

4 444. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
5 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
6 and Kern County.

7 445. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
8 report, and prevent suspicious orders of opioids.

9 446. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
10 conspiracy by increasing the volume of opioid sales in the United States through creating a market
11 for non-medical use of opioids of epidemic proportions.

12 447. Many of the Manufacturing Defendants are members, participants, and/or sponsors
13 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
14 the HDA to give further assistance to the conspiracy.

15 448. The Manufacturing Defendants hid from the general public and suppressed and/or
16 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
17 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
18 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

19 449. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
20 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
21 to commit acts of fraud.

22 450. Indeed, for the Defendants’ fraudulent scheme to work, each of the Defendants had
23 to agree to implement similar tactics.

24 451. By intentionally refusing to report and halt suspicious orders of their prescription
25 opioids, Defendants engaged in a fraudulent scheme.

26 452. Nevertheless, in order to increase sales of their opioid products in furtherance of the
27 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
28 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,

1 and were actually being diverted into the market of non-medical use.

2 453. Defendants further unlawfully marketed opioids in California and Kern County in
3 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
4 dissemination of false and misleading information about the safety and efficacy of long-term opioid
5 use through, among other things: (a) the use of “Front Groups” that appeared to be independent of
6 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
7 continuing medical education (“CME”) programs controlled and/or funded by the Defendants; (d)
8 hiring and deploying so-called “key opinion leaders” or “KOLs” who were paid by the Defendants
9 to promote their message; and (e) the “detailing” activities of the Defendants’ sales forces, which
10 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
11 physicians lacking the expertise of pain care specialists.

12 454. Each of the Front Groups helped disguise the role of Defendants by purporting to be
13 unbiased, independent patient-advocacy and professional organizations in order to disseminate
14 patient education materials, a body of biased and unsupported scientific “literature,” and “treatment
15 guidelines” that promoted the Defendants’ false messages.

16 455. Each of the KOLs were physicians chosen and paid by each of the Defendants to
17 influence prescribers’ habits by promoting the Defendants’ false message through, among other
18 things, writing favorable journal articles and delivering supportive CMEs as if they were
19 independent medical professionals, thereby further obscuring the Defendants’ role in the
20 conspiracy.

21 456. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
22 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
23 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
24 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
25 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
26 were industry-friendly and would work together with the Defendants to advance the conspiracy.

27 457. Defendants’ conspiracy and acts in furtherance thereof are alleged in detail in this
28 Complaint, including, without limitation, in Plaintiff’s Counts for violations California Statutes.

1 Such allegations are specifically incorporated herein.

2 458. Defendants acted with a common understanding or design to commit unlawful acts,
3 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
4 proximately caused the injuries alleged herein.

5 459. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
6 reasonable or lawful excuse.

7 460. Defendants conduct in furtherance of the conspiracy described herein was not mere
8 parallel conduct because each Defendant acted directly against their commercial interests in not
9 reporting the unlawful distribution practices of their competitors to the authorities, which they had
10 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
11 actual or tacit agreement between the Defendants that they would not report each other to the
12 authorities so they could all continue engaging in their unlawful conduct.

13 461. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
14 thereof, caused the direct and foreseeable losses alleged herein.

15 462. Defendants' misconduct alleged in this case is ongoing and persistent.

16 463. As a result of Defendants' conspiracy, Kern County is entitled to compensatory
17 damages in an amount to be proved at trial.

18 464. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
19 fraudulent, entitling Kern County to punitive damages.

20 ///

21 ///

22 ///

23 **SIXTH CAUSE OF ACTION**

24 **(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

25 465. Plaintiff realleges and incorporates herein by reference each and every allegation in
26 paragraphs 1 through 463 above as if set forth fully herein.

27 466. California Business & Professions Code § 17500 makes it unlawful for a business
28 to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning

1 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
2 exercise of reasonable care should be known, to be untrue or misleading.”

3 467. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
4 designed to disseminate false or misleading statements designed to promote the belief that opioid
5 drugs could safely be used in a non-addictive manner.

6 468. By way of example, Actavis’s predecessor created a patient brochure for Kadian in
7 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome
8 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

9 469. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back
10 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
11 claimed that it is “less likely if you have never had an addiction problem.”

12 470. Cephalon and Purdue sponsored research and publications that falsely and
13 deceptively stated opioids did not have “ceiling dose.”

14 471. Purdue created websites, available to the public that instructed patients to seek new
15 medical providers out if their current provider would not increase their dose.

16 472. Defendants’ false and deceptive advertising practices resulted in increased opioid
17 dosages being prescribed to Kern County’s residents, increasing the incidence of opioid addiction
18 and overdose in Kern County.

19 473. Distributor Defendants also repeatedly omitted material information and/or falsely
20 represented that they were effectively preventing diversion and were monitoring, reporting, and
21 preventing suspicious orders.

22 474. As alleged above, Defendants’ statements about the risks associated with opioid use
23 were not supported by or were contrary to the scientific evidence.

24 475. As alleged above, each Defendant’s conduct, separately and collectively, was likely
25 to deceive California payors who purchased or covered the purchase of opioids.

26 476. Kern County seeks restitution and injunctive relief under California Business &
27 Professions Code § 17535.

28 477. Kern County also seeks an order assessing a civil penalty of two thousand five

1 hundred dollars (\$2,500) against Defendants for each violation of California's False Advertising
2 Law pursuant to California Business & Professions Code § 17536.

3 **SEVENTH CAUSE OF ACTION**
4 **(Negligent Failure to Warn— Against Manufacturer Defendants)**

5 478. Plaintiff realleges and incorporates herein by reference each and every allegation in
6 paragraphs 1 through 476 above as if set forth fully herein.

7 479. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
8 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
9 adequately warning the medical profession about the risk of addiction from the use of opioid
10 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
11 cancel out, and render meaningless any written warnings given about the risk of addiction from the
12 use of opioid products.

13 480. Defendants breached their duty to exercise reasonable and ordinary care by failing
14 to adequately warn the medical profession about the risk of addiction from the use of opioid
15 products, including by overpromoting and over-marketing opioid products in a manner so as to
16 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
17 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
18 products in situations and for patients who should not have been using those drugs or should have
19 used them only as a last resort before other means were used or other less addictive and dangerous
20 drugs were prescribed.

21 481. As a direct and proximate consequence of Defendants' negligent failure to warn,
22 and overpromoting and over-marketing the use of prescription opioid products, there is now a
23 national opioid addiction epidemic, including in Kern County. The People, as a further direct and
24 proximate consequence and result thereof, sustained injuries and damages including but not limited
25 to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs,
26 law and regulatory enforcement costs, opioid disposal programs, and measures for prevention of
27 further opioid abuse and addiction.

28 482. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and

1 fraudulent, entitling Kern County to punitive damages.

2 **EIGHTH CAUSE OF ACTION**
 3 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler**
 4 **Defendants)**

4 483. Plaintiff realleges and incorporates herein by reference each and every allegation in
 5 paragraphs 1 through 481 above as if set forth fully herein.

6 484. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
 7 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
 8 possess a right to payment from Purdue.

9 485. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
 10 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
 11 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
 12 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

13 486. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
 14 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
 15 including Plaintiff.

16 487. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
 17 them pursuant to California Civil Code § 3439.04(a)(1).

18 **NINTH CAUSE OF ACTION**
 19 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

20 488. Plaintiff realleges and incorporates herein by reference each and every allegation in
 21 paragraphs 1 through 486 above as if set forth fully herein.

22 489. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
 23 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
 24 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
 25 of its judgment against Purdue entered in this action.

26 490. After the Sackler Defendants became aware in or about 1999 that Purdue faced
 27 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
 28 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping

Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other opioid-containing medications via distributions from Purdue to shareholders, including the Sackler Defendants and their extended family.

491. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.

492. Purdue and the Sackler Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and proximately caused the injuries alleged herein.

493. Purdue and the Sackler Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

494. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the judgment entered in this action.

495. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to compensatory damages in an amount to be proved at trial.

496. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Kern County and the People respectfully request judgment in their favor granting the following relief:

- a) Entering Judgment in favor of Kern County and the People in a final order against each of the Defendants;
- b) An award of actual and consequential damages in an amount to be determined at trial;
- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;

- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) An order enjoining Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff may obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Kern County for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff’s judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;
- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;

- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and
- v) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Dated: March 27, 2019

ROBINS KAPLAN LLP

By: 

Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT C

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF WESTMINSTER;
(LO ESTÁ DEMANDANDO EL DEMANDANTE): and THE PEOPLE OF THE STATE OF CALIFORNIA, by and through Westminster City Attorney Richard D. Jones

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
 (El nombre y dirección de la corte es):

San Francisco County Superior Court
 Civic Center Courthouse
 400 McAllister Street
 San Francisco, CA 94102-4515

CASE NUMBER:
 (Número del Caso): 19-574864

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800
 Lucas A. Messenger, Bar No. 217645
 ROBINS KAPLAN LLP
 Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

CLERK OF THE COURT

Clerk, by

(Secretario)

DE LA VEGA-NAVARRO, Rossaly

Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

(SEAL)

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
 2. ☐ as the person sued under the fictitious name of (specify):

3. ☐ on behalf of (specify):

under: ☐ CCP 416.10 (corporation)

☐ CCP 416.20 (defunct corporation)

☐ CCP 416.40 (association or partnership)

☐ other (specify):

☐ CCP 416.60 (minor)

☐ CCP 416.70 (conservatee)

☐ CCP 416.90 (authorized person)

4. ☐ by personal delivery on (date):

SUM-200(A)

SHORT TITLE: City of Westminster, et al. v. Purdue
Pharma L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

Page _____ of _____
 Page 1 of 1

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Attorneys for Plaintiffs City of Westminster and The
People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

CITY OF WESTMINSTER; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through
Westminster City Attorney Richard D.
Jones,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF

Case No. CGC - 19 - 574864

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;

ENDORSED
FILED
Superior Court of California
County of San Francisco

MAR 28 2019

CLERK OF THE COURT
BY: ROSSALY DE LA VEGA
Deputy Clerk

MEMBERS OF THE RAYMOND SACKLER FAMILY; MORTIMER D.A. SACKLER, an individual; KATHE A. SACKLER, an individual; IRENE SACKLER LEFCOURT, an individual; BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual; DAVID A. SACKLER, an individual; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC.; ACTAVIS LLC; ALLERGAN PLC; ALLERGAN, INC.; ALLERGAN USA, INC.; INSYS THERAPEUTICS, INC.; MALLINCKRODT, PLC; MALLINCKRODT, LLC; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; MCKESSON CORPORATION; and DOES 1-100, inclusive,

Defendants.

8. FRADULENT TRANSFER; and

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Westminster Through Illicit Channels	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Westminster Through Illicit Channels.....	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Westminster.....	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff City of Westminster (hereinafter, “Westminster”) has been particularly hard hit, causing Westminster to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. Westminster, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California (the “People,” and together with Westminster, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants’ efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. Westminster has seen increased costs, including, but not limited to, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) Westminster city services related to infants born with opioid-related medical conditions; (d) Westminster city services related to welfare and foster care for children whose parents suffer from opioid-related disability or

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 incapacitation, including costs of related legal proceedings; (e) public safety connected to the opioid
2 epidemic within Westminster, including police, emergency response services, and detention
3 centers; (f) increased burden on Westminster's code enforcement programs; and (g) extensive
4 clean-up of public parks, spaces, and facilities. At the same time, Westminster has seen a reduction
5 to tax revenues caused by the epidemic created by the Defendants. Almost every citizen of
6 Westminster has been affected. The resulting damage to Westminster was directly and foreseeably
7 caused by Defendants' actions.

8 7. These increased costs could have been—and should have been—prevented by the
9 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
10 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
11 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
12 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
13 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
14 protecting opioids from theft, misuse, and diversion.

15 8. Instead of acting with reasonable care and in compliance with their legal duties,
16 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
17 process.

18 9. At the same time, Defendants flooded the market with false statements designed to
19 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
20 claims were false.³

21 10. Defendants' actions have not only caused significant costs, but have also created a
22 palpable climate of fear, distress, dysfunction and chaos among Westminster residents where opioid
23 diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

24 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
25 and/or unlawful conduct.

26
27
28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. Westminster, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. Westminster has standing to recover damage incurred because of Defendants' actions and omissions. Westminster has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical’s products and Janssen’s profits inure to J&J’s benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as “Actavis”).

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

1 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
2 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
3 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
4 California with the California Secretary of State.

5 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
6 principal place of business located in Chandler, Arizona.

7 38. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source
8 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
9 United States, including California. Subsys was indicated by the FDA for the treatment of
10 breakthrough cancer pain that other opioids could not eliminate.

11 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
12 bribe physicians with purported speaking fees for marketing and education events in exchange for
13 them prescribing Subsys for off-label uses. Insys’ founder and several other former Insys executives
14 were recently indicted by federal prosecutors on racketeering charges, alleging that these
15 individuals approved and fostered fraudulent behavior against insurance companies and also
16 conspired to bribe practitioners in various states. Insys Group is registered to do business in
17 California with the California Secretary of State.

18 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
19 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
20 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
21 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
22 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

23 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
24 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
25 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
26 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
27 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
28 Products are registered to do business in California with the California Secretary of State.

42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and Mallinckrodt are the “Manufacturer Defendants.”

C. The Distributor Defendants

43. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

44. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with Westminster and its residents, and has purposefully availed itself of the advantages of conducting business with and within Westminster. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

45. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

46. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with Westminster and its residents, and has purposefully availed itself of the advantages of conducting business with and within Westminster. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

48. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with Westminster and its residents, and has purposefully availed itself of the advantages of conducting business with and within Westminster. McKesson is in the chain of distribution of prescription opioids. McKesson

1 Corporation is registered to do business in California with the California Secretary of State.

2 49. The data which reveals and/or confirms the identity of the other wrongful opioid
3 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
4 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
5 voluntarily disclose the data necessary to identify with specificity the transactions which will form
6 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

7 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
8 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
9 listed on the New York Stock Exchange and their principal business consists of the nationwide
10 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
11 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
12 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
13 suspicious orders. Westminster has reason to believe each has engaged in unlawful conduct which
14 resulted in the distribution, dispensing, and diversion of prescription opioids into Westminster.
15 Westminster names each of the "Big 3" herein as defendants and places the industry on notice that
16 Westminster is acting to abate the public nuisance plaguing its community. Distributor Defendants
17 have had substantial contacts and business relationships with the People. Distributor Defendants
18 have purposefully availed themselves of business opportunities within Westminster.

19 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
20 Defendants."

21 **D. The Doe Defendants**

22 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
23 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
24 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
25 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
26 is informed and believes, and on such information and belief alleges, that each of the Defendants
27 named as a DOE is responsible in some manner for the events and occurrences alleged in this
28 Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

53. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance in Westminster, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

54. Venue is proper in this Court because Defendants transact business in California and San Francisco County, and some of the acts complained of occurred in this venue. Furthermore, Defendant Distributor McKesson's principal place of business is in San Francisco County, and McKesson conducted business and continues to do business throughout the United States and in the State of California by regularly and continuously distributing prescription opioids throughout the State of California.

IV. GENERAL FACTUAL ALLEGATIONS**A. An Overview of the Opioid Epidemic**

55. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death."⁵

56. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

57. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

1 director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have
2 very, very high inherent risks . . . and there's no such thing as a fully safe opioid."⁶

3 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
4 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
5 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

6 59. Before the 1990s, generally accepted standards of medical practice dictated that
7 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
8 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
9 patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as
10 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
11 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
12 generally did not prescribe opioids for chronic pain.

13 60. The market for chronic pain patients, however, was much larger, and to take
14 advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for
15 chronic pain.⁷

16 61. As described herein, Defendants engaged in conduct that directly caused doctors to
17 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
18 obligations to prevent diversion of the highly addictive substance.

19 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
20 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
21 for every person in the United States to have a bottle of pills. This represents an increase of 300%
22 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
23 were dispensed per 100 persons.

24 63. Many Americans, including Californians and residents of Westminster, are now
25

26 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

27 ⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times
28 (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United
 2 States, an increase of more than 22 percent over the previous year. The New York Times reported
 3 in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly
 4 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 5 a public health emergency by the President of the United States. The wave of opioid addiction was
 6 created by the increase in prescriptions.

7 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 8 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 9 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 10 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 11 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 12 80 percent of people who use heroin first misused prescription opioids.

13 65. Drug overdose deaths among all Americans increased more than 200 percent
 14 between 1999 and 2015.

15 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 16 there were 4,654 total opioid overdose deaths in 2016.⁹

17 ///

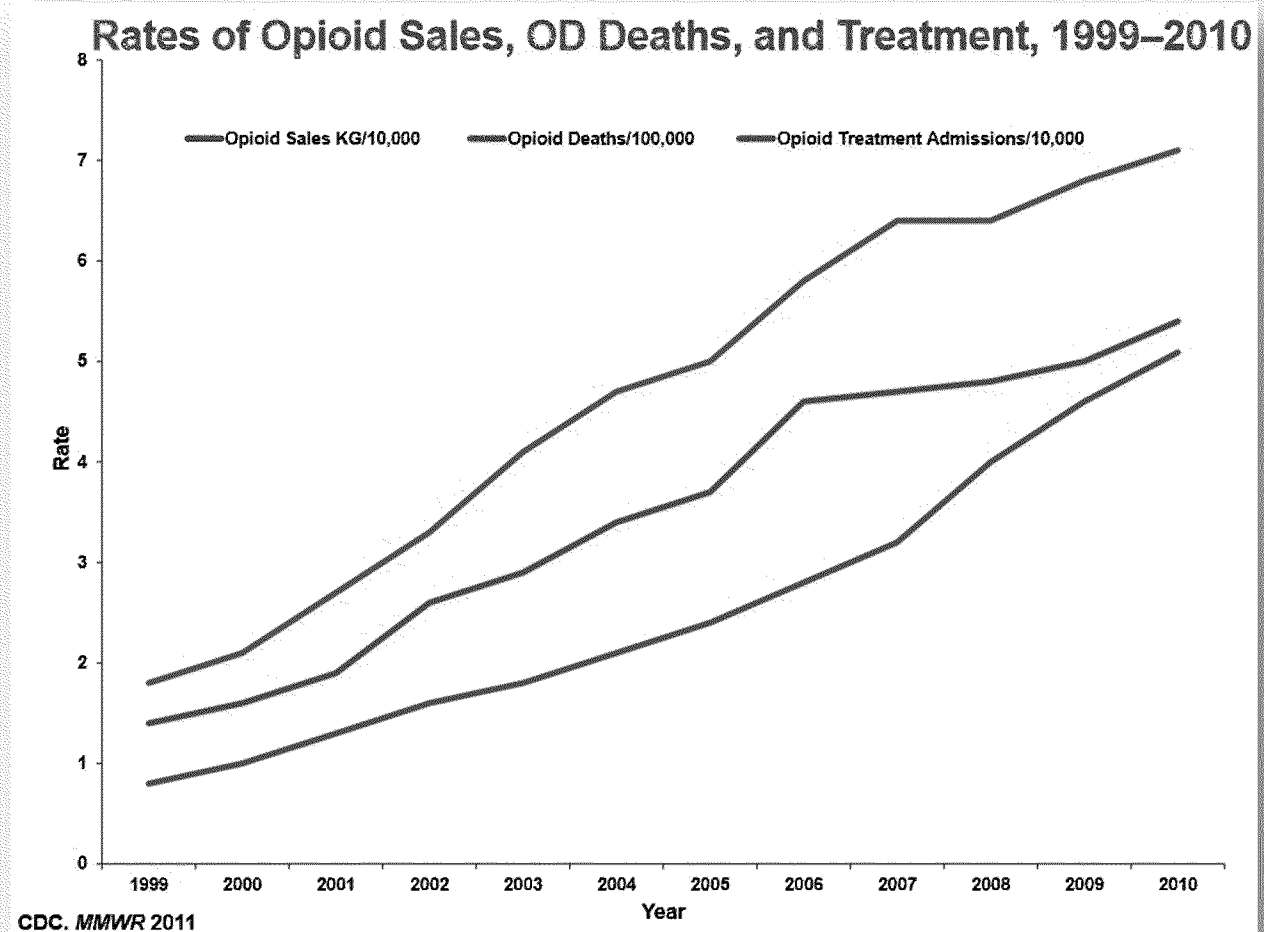
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26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*, N.Y.
 27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, *California Opioid Summary*, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in Westminster, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants’ messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
2 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
3 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
4 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
5 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
6 carried a low, or no, risk of addiction.

7 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
8 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
9 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
10 of actual addiction began appearing, and advocated that the signs of addiction should be treated
11 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
12 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
13 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
14 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
15 opioid use, including the supposed ability of opioids to improve function and quality of life, even
16 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
17 claims.

18 75. These statements were not only unsupported by or contrary to the scientific
19 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
20 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
21 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

22 76. The Manufacturer Defendants began their marketing schemes decades ago and
23 continue them today.

24 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
25 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
26 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
27
28

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
 24

25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 27 29, 2017).

28 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient
 Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 100. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
6 unbranded advertising stated that “People who take opioids as prescribed usually do not become
7 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use.”

10 101. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 104. For example, the New York Attorney General (“NY AG”) found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in Westminster and doctors treating residents of Westminster.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 _____
28 ²³ Dr. Portenoy was a member of the board of the APF.

²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 119. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 120. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 121. On information and belief, AAPM is viewed internally by Endo as “industry

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26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 122. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

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27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in Westminster during the relevant time period, are still available online, and were
 12 often reprinted in the Journal of Pain, which is the official journal of the American Pain Society.
 13 The Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 126. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 128. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 129. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 130. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 131. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
25 marketing materials along with the rights to Kadian, it appears that Actavis
26 continued to use this brochure in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
28 People Living with Pain (2007), which suggests that addiction is rare and
limited to extreme cases of unauthorized dose escalations, obtaining
duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Westminster, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 138. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain *is under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in Westminster, to PartnersAgainstPain.com, which contained false
14 and misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 **Deceptive Claims of Pseudoaddiction**

22 139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
some of its proponents” and reported that despite the fact that Endo trained its sales representative
to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
Management testified to [the NY AG] that he was not aware of any research validating the
‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 141. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including Westminster the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

1 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
 2 widely believed by doctors to detect and deter abuse—“for improving outcomes related to
 3 overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that
 4 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
 5 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
 6 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

7 143. To underplay the risk and impact of addiction and make doctors feel more
 8 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
 9 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
 10 failed to disclose the increased difficulty of stopping opioids after long-term use.

11 144. For example, on information and belief, a 2011 non-credit educational program
 12 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
 13 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

14 145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
 15 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
 16 by gradually decreasing the dose of medication during discontinuation” without mentioning any
 17 hardships that might occur.³⁸ This publication was available on APF’s website until the
 18 organization dissolved in May 2012.

19 146. Detailers for Janssen have told and continue to tell doctors in California, including
 20 Westminster, that their patients would not experience withdrawal if they stopped using opioids.

21 **Deceptive Minimization of Opioid Withdrawal**

22 147. The Manufacturer Defendants also deceptively minimized the significant symptoms
 23 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
 24 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
 25 understated the difficulty of tapering, particularly after long-term opioid use.

26 148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

27
 28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
 December 19, 2017).

recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that “more than a few days of exposure to opioids significantly increases hazards” and “each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk

149. The Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants, are described below:

- a. On information and belief, Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’ acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in Westminster that they should increase the dose of OxyContin,
rather than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was *no* evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in Westminster, that Opana ER is harder to abuse and given demonstrations to
22 nurse practitioners about Opana ER’s purported abuse deterrent properties.

24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-
push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou
ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those statements to be false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

158. Because Orpana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.

159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse, and that its abuse deterrent properties can be defeated.

160. These statements and omissions by Purdue are false and misleading, and conflict with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 27 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 28 430.

⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose
 epidemic*, Business Insider (Mar. 14, 2016), available at [http://www.businessinsider.com/robert-califf-
 abuse-deterrent-drugs-have-a-big-flaw-2016-3](http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3) (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in Westminster, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

174. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this
26

27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by Westminster.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

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27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

28 ⁵² *Id.*

1 misrepresentations deceived and continue to deceive doctors and patients in California, including
2 in Westminster, about the risks and benefits of long-term opioid use. California doctors confirm
3 this. Studies also reveal that many doctors and patients are not aware of or do not understand these
4 risks and benefits. Indeed, patients often report that they were not warned they might become
5 addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than
6 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.
7 Plaintiff is informed and believes that California residents were never told that they might become
8 addicted to opioids when they started taking them, were told that they could easily stop using
9 opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

10 192. Numerous doctors and substance abuse counselors in California note that many of
11 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
12 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
13 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
14 for opioid addiction.

15 193. The Manufacturer Defendants knew and should have known that their
16 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
17 when they made them.

18 194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
19 properties of their opioids caused and continue to cause doctors in California, including doctors in
20 Westminster, to prescribe opioids for chronic pain conditions such as back pain, headaches,
21 arthritis, and fibromyalgia, rather than prescribing less addictive medications. Absent
22 Manufacturers Defendants' deceptive marketing scheme, these doctors would not have prescribed
23 as many opioids to as many patients, and there would not have been as many opioids available for
24 misuse and abuse or as much demand for those opioids.

25 195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
26 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
27 California, including in Westminster. Opioids are the most common means of treatment for chronic
28 pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per

1 year are prescribed a long-acting opioid.

2 196. In California, including Westminister, Manufacturer Defendants' deceptive
3 marketing of the abuse-deterrent properties of their opioids during the past few years has been
4 particularly effective. For example, one survey reports that pain specialists were more likely to
5 recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically
6 because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent
7 properties were using more of it than those who did not know it was an AD opioid. Although sales
8 of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold
9 in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or
10 approximately 25% in opioid sales revenue in 2015).

11 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 198. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 199. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 200. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 201. Diversion can occur at any point in the opioid supply chain.

4 202. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 205. Opioid diversion occurs at an alarming rate in the United States.

23 206. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 **210.** In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 211. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 212. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for Westminster and the people therein.

25 213. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

1 214. Thus, all opioid distributors are required to maintain effective controls against
2 opioid diversion. They are required to create and use a system to identify and report to the California
3 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
4 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
5 and/or orders of unusual frequency. To comply with these requirements, distributors must know
6 their customers, must conduct due diligence, must report suspicious orders, and must terminate
7 orders if there are indications of diversion.

8 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
9 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
10 their obligations under the CSA.

11 216. Under the CSA, anyone authorized to handle controlled substances must track
12 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
13 automated drug reporting system that records and monitors the flow of Schedule II controlled
14 substances from the point of manufacture through distribution to the point of sale. ARCOS
15 accumulates data on distributors' controlled substances and transactions, which are then used to
16 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
17 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
18 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
19 and current record of each substance manufactured, imported, received, sold, delivered, exported,
20 or otherwise disposed of.

21 217. Plaintiff does not bring causes of action based on violations of federal statutes and
22 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
23 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
24 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
25 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
26 prescription opioids.

1. The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Westminster Through Illicit Channels

218. The Distributor Defendants have been and continue to be well-aware of problems posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes that the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. The distributors are also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor Defendants should look for in order to identify potential diversion.

219. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

220. Since 2008, the DEA also has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 Westminster and its residents. Each Distributor Defendant knew or should have known that the
7 opioids reaching Westminster were not being consumed for medical purposes and that the amount
8 of opioids flowing to Westminster was far in excess of what could be consumed for medically
9 necessary purposes.

10 232. The Distributor Defendants negligently or intentionally failed to adequately control
11 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
12 substances would have anticipated the danger of opioid diversion and protected against it by, for
13 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
14 greater oversight, security, and control of supply channels; (c) looking more closely at the
15 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
16 amounts greater than the populations in those areas would warrant; (d) investigating demographic
17 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
18 Westminster; (e) providing information to pharmacies and retailers about opioid diversion; and (f)
19 in general, simply following applicable statutes, regulations, professional standards, and guidance
20 from government agencies and using a little bit of common sense.

21 233. On information and belief, the Distributor Defendants made little to no effort to visit
22 the pharmacies servicing the areas around Westminster to perform due diligence inspections to
23 ensure that the controlled substances the Distributor Defendants had furnished were not being
24 diverted to illegal uses.

25 234. On information and belief, the compensation the Distributor Defendants provided
26 to certain of their employees was affected, in part, by the volume of their sales of opioids to
27 pharmacies and other facilities servicing the areas around Westminster, thus improperly creating
28 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid

1 abuse.

2 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
3 flooding the market in and around Westminster with highly addictive opioids would allow opioids
4 to fall into the hands of children, addicts, criminals, and other unintended users.

5 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
6 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
7 and death. It was also reasonably foreseeable that many of these injuries would be suffered by
8 Westminster residents, and that the costs of these injuries would be borne by Westminster.

9 237. The Distributor Defendants knew or should have known that the opioids being
10 diverted from their supply chains would contribute to the opioid epidemic faced by Westminster,
11 and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
12 addiction, demand, illegal transactions, economic ruin, and human tragedy.

13 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
14 and around Westminster, but, on information and belief, they nevertheless persisted in a pattern of
15 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
16 with such frequency that they knew or should have known these commonly abused controlled
17 substances were not being prescribed and consumed for legitimate medical purposes.

18 239. The use of opioids by Westminster residents who were addicted or who did not have
19 a medically necessary purpose could not have occurred without the knowing cooperation,
20 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
21 Defendants adhered to effective controls to guard against diversion, Westminster and its residents
22 would have avoided significant injury.

23 240. The Distributor Defendants made substantial profits over the years based on the
24 diversion of opioids into Westminster. The Distributor Defendants knew that Westminster would
25 be unjustly forced to bear the costs of these injuries and damages.

26 241. The Distributor Defendants' intentional distribution of excessive amounts of
27 prescription opioids showed an intentional or reckless disregard for the safety of Westminster and
28 its residents. Their conduct poses a continuing threat to the health, safety, and welfare of

Westminster.

242. The state laws at issue here are public safety laws.

243. The Distributor Defendants' violations constitute prima facie evidence of negligence under state law.

2. The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Westminster Through Illicit Channels

244. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under California law.

245. In addition to a common law duty to exercise reasonable care in the promotion and marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts determined by the Board. *See* 16 CCR 1782.

246. On information and belief, for over a decade the Manufacturer Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Manufacturer Defendants breached their duties under state law.

247. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer

1 Defendants built receipt of this information into the payment structure for the opioids provided to
2 the opioid distributors.

3 248. The Manufacturer Defendants' actions and omission in failing to effectively prevent
4 diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful
5 diversion of opioids into Westminster.

6 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

7 249. As the demand for prescription opioids grew, fueled by their potency and purity,
8 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
9 traveling across state, city, and county lines in a variety of ways.

10 250. First, prescriptions written in one state would, under some circumstances, be filled
11 in a different state. But even more significantly, individuals transported opioids from one
12 jurisdiction specifically to sell them in another.

13 251. When authorities in one state cracked down on opioid suppliers, out-of-state
14 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
15 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
16 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
17 practice became so common that authorities dubbed these individuals "prescription tourists."

18 252. The facts surrounding numerous criminal prosecutions illustrate this common
19 practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught
20 flying to California in attempts to obtain additional sources of supply for their drug operation which
21 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

22 253. In another example, a man from Warren County, Ohio, who was sentenced to four
23 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
24 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
25 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a

26 _____
27 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

28 ⁵⁹ Andrew Welsh-Huggins, Associated Press, '*Prescription Tourists* Thwart States' Crackdown on Illegal Sale of Painkillers, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-

1 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
2 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
3 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
4 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
5 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
6 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

7 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
8 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
9 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
10 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
11 customers were from other states.⁶³

12 255. In yet another case, defendants who operated a pill mill in south Florida within
13 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
14 transported oxycodone back to the area for both use and distribution by local drug trafficking
15 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
16 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
17 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
18 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
19 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
20

21 [painkillers/#.WtdyKE2Wy71](#) (last updated July 8, 2012, 12:28 PM).

22 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
<http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
23 accessed July 25, 2018).

24 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
25 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

26 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
27 accessed July 25, 2018).

28 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
[patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

1 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
 2 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
 3 Kentucky residents.”⁶⁵

4 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
 5 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
 6 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
 7 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
 8 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
 9 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
 10 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
 11 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
 12 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

13 257. While the I-75 corridor was well utilized, prescription tourists also came from other
 14 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
 15 mills come from as far away as Arizona and Nebraska.⁷⁰

16 258. Similar pipelines developed in other regions of the country. For example, the I-95
 17 corridor was another transport route for prescription pills. As the director of the Maine Drug
 18 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
 19 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
 20

21 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s*
 24 *Deadliest Drug Epidemic* 171 (2016).

25 ⁶⁷ *Id.* at 172

26 ⁶⁸ *Id.* at 171

27 ⁶⁹ *Id.*

28 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
 Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
 (last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
 Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
 (last accessed July 25, 2018)

1 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
2 Ohio, and Kentucky.

3 259. Along the west coast, over a million pills were transported from the Lake Medical
4 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²
5 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
6 Everett-based dealer who received the pills from southern California wore a diamond necklace in
7 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
8 OxyContin—connecting Los Angeles and Washington state.

9 260. Defendants certainly were aware, or should have been aware, that pill mills from
10 around the country were pushing its products. Defendants purchased nationwide, regional, state,
11 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
12 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
13 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
14 compute, and track their competitors' sales, and to compare and analyze market share information.

15 261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
16 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
17 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
18 regarding competing drugs, and analyzed the market share of those drugs.

19 262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
20 rewarded sales representatives who happened to have pill mills within their territories, enticing
21 those representatives to look the other way even when their in-person visits to such clinics should
22 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
23 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
24 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
25 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric

26
27 ⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and
Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

28 ⁷³ *Id.*

1 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
2 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
3 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
4 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
5 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

6 ⁷⁴

7 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
8 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
9 sales representative "it was packed with a line out the door, with people who looked like gang
10 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
11 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
12 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
13 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
14 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
15 2010 to inform the authorities.

16 264. Abundant evidence, thus, establishes that prescription opioids migrated between
17 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
18 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
19 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
20 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
21 prescription opioid pills were hard to get in one area, they migrated from another. The
22 manufacturers and distributors were fully aware of this phenomenon and profited from it.

23 265. Defendants each knew or should have known that opioid diversion and abuse was
24 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide

25 _____
26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

1 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
2 allowed to continue the unlawful diversion of opioids into Westminster.

3 **G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the**
4 **Harm Alleged Herein and Substantial Damages**

5 266. As the Manufacturer Defendants' efforts to expand the market for opioids increased,
6 so have the rates of prescription and the sale of their products, as well as the rates of opioid-related
7 substance abuse, hospitalization, and death among Westminster residents and across the nation.
8 Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of
9 opioids into communities like Westminster, fueling the epidemic.

10 267. There is a "parallel relationship between the availability of prescription opioid
11 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
12 associated adverse outcomes."⁷⁷

13 268. Opioids are widely diverted and improperly used, and the widespread use of the
14 drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

15 269. The epidemic is "directly related to the increasingly widespread misuse of powerful
16 opioid pain medications."⁷⁹

17 270. The increased abuse of prescription opioids—along with growing sales—has
18 contributed to a large number of overdoses and deaths.

19 271. As shown above, the opioid epidemic has escalated in Westminster with devastating
20 effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants'
21 increased distribution of opioids.

22 272. Because of the well-established relationship between the use of prescription opioids
23 and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to
24 Westminster and areas from which opioids are being diverted to Westminster, has caused the opioid
25 epidemic to include heroin addiction, abuse, and death.

26 _____
27 ⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N.
Eng. J. Med. 241 (2015).

28 ⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Westminster.

274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Westminster.

275. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in Westminster.

276. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in Westminster. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by Westminster and residents of Westminster.

277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Westminster seeks relief, as alleged herein. Westminster also seeks the means to abate the epidemic created by the Defendants.

278. Westminster seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

279. Westminster seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

280. Westminster seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

281. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

282. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at <https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and->

283. The community-based problems require community-based solutions that have been limited by budgetary constraints.

284. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon Westminster.

285. The opioid epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

286. The Defendants have abandoned their duties imposed by the law, taken advantage of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in Westminster.

287. In the course of conduct described in this Complaint, Defendants have acted with oppression, fraud, and malice, both actual and presumed.

H. The Impact of Opioid Abuse on Westminster

288. Defendants' creation, through false and misleading advertising and a failure to prevent diversion, of a virtually limitless opioid market has significantly harmed Westminster and resulted in an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be associated with the consumption of a counterfeit version of the prescription drug Norco (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has

[effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf](#) (last accessed January 8, 2018).

1 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
2 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
3 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further
4 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
5 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
6 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
7 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
8 related overdoses, with 55% of those resulting from prescription opioids.

9 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
10 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
11 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
12 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
13 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

14 291. Even Westminster's youngest residents bear the consequences of the opioid abuse
15 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
16 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
17 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
18 Many Westminster women have become addicted to prescription opioids and have used these drugs
19 during their pregnancies. As a result, many Westminster infants suffer from opioid withdrawal and
20 Neonatal Abstinence Syndrome ("NAS").⁸⁵

21 _____
22 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
23 *year*, LA Times (Oct. 27, 2014), available at [http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html)
24 [prescription-hospital-er-20141026-story.html](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html) (last accessed December 21, 2017).

25 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
26 *The Opioid Crisis in Indian Country*, at 37, available at
27 <https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
28 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US, 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at

292. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation can cost thousands of dollars for each occurrence.

293. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

294. Many of the parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

295. Opioid addiction is now the primary reason that Californians seek substance abuse treatment, and admissions to drug treatment facilities in California more than doubled from 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one facility in northern California, up to 90% – started on legal opioid prescriptions.

296. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in California. California faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]” and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting worse.

297. There is little doubt that each Defendant's deceptive marketing and distribution scheme has precipitated this public health crisis in California, including Westminster, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids

<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 has created a population of patients physically and psychologically dependent on them (the
2 demand). And when those patients can no longer afford or legitimately obtain opioids, they often
3 turn to the street to buy prescription opioids or even heroin.

4 298. The effects of Defendants' deceptive marketing and distribution scheme has further
5 impacted Plaintiff in a foreseeable way such that Westminster must devote increased resources to
6 the burden of the addicted homeless who commit drug and property crimes, to feed their addiction.
7 For example, tax dollars are required to maintain public safety of places where the addicted
8 homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required
9 to fight the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
10 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
11 *aureus* (MRSA) are spread by opioid abuse.

12 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
13 have recruited addicts nationally with false and misleading promises of the medically supervised
14 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
15 effective rehabilitation available in beautiful California communities, including Westminster.
16 These for-profit rehabilitation businesses failed to provide proper rehabilitation facilities.
17 Investigations revealed that many have provided substandard care including use of physicians who
18 have had their license revoked, operating staffs which do not actually supervise patients, and
19 facilities that do not operate programs for addicts. Instead these facilities bring addicts to California,
20 provide substandard care as long as there are third party payments available, and then throw them
21 out of the facilities to be homeless. These addicts brought to California, including Westminster, by
22 the substandard rehab industry, have further contributed to the public's burden by discharging
23 addicted homeless into the community who require further care and rehabilitation at the public's
24 expense, and who commit crimes in California in order to further feed their addiction. The
25 manufacturer and distributor Defendants were aware at all relevant times when they deceptively
26 marketed their products as non-addictive that such addiction would be highly difficult to overcome.
27 Defendants knew or should have known that municipalities, including Westminster, would bear the
28 burden of costs associated with rehabilitation business of all types.

300. The role of Defendants’ deceptive marketing and distribution scheme in causing this public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.” And in August 2016, the former U.S. Surgeon General expressly connected the “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment specialists, and law enforcement and public health officials confirm that prescription opioids lawfully prescribed by doctors have fueled this epidemic.

301. Absent each Defendant’s deceptive marketing scheme and improper distribution, opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not only engaged in false advertising, they have also created or assisted in the creation of a public nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the present is part of its deceptive marketing and distribution scheme and subjects that Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

303. Accordingly, Defendants’ conduct, both individually and collectively, has violated and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Westminster does not seek to limit the ability of doctors in California to prescribe opioids. Westminster does not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, Westminster seeks an order requiring

1 Defendants to cease their unlawful promotion and distribution of opioids, to correct their
2 misrepresentations, and to abate the public nuisance they have created. To redress and punish
3 Defendants' previous and current violations of law that cause and continue to cause harm to
4 Westminster, Plaintiff seeks a judgment requiring Defendants to pay civil penalties, and any fees
5 or costs permitted under law.

6 304. By this action, Westminster further seeks to recoup tax dollars spent already for the
7 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
8 impact on this county and its communities, and to abate the opioid nuisance so Westminster will
9 not be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
10 wrongful conduct as alleged herein.

11 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
12 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
13 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
14 California spiked by 34% from 2011 to 2013.

15 306. Opioid abuse also contributes to a range of social problems including physical and
16 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
17 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
18 unemployment, and despair. More and more Westminster resources are needed to combat these
19 problems. The prescription opioid crisis also diminishes Westminster's available workforce,
20 decreases productivity, increases poverty, and requires greater governmental expenditures by
21 Westminster.

22 307. The prescription opioid crisis has directly financially injured Westminster. The
23 crisis has led to an increased demand for, *inter alia*, security services (such as police, EMS,
24 detention), child protective services, health services, clean-up services, and legal services.
25 Westminster has also had to hire additional staff and expend additional resources to manage the
26 demand.

27 308. Westminster's medical services have seen an increase in opioid-related health
28 problems among Westminster residents, including, but not limited to, infants born with opioid-

1 related medical conditions. This has resulted in increased demand and increased expenses.

2 309. Westminster has also suffered substantial financial damages in the form of lost
3 productivity of Westminster employees and residents, lost economic activity, lost reputation and
4 good will, and the lost opportunity for growth. These damages have been suffered and continue to
5 be suffered directly by Westminster.

6 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
7 their homes and their families. Some will get treatment and fewer will successfully complete it;
8 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
9 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
10 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
11 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
12 drug transactions; or dying from opioid-induced heart or neurological disease.

13 311. Westminster also has suffered substantial financial damages in the form of lost taxes
14 paid by its residents and businesses as a result of lost earnings and productivity.

15 312. While the use of opioids has taken an enormous toll on Westminster and its
16 residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11
17 billion in revenue for drug companies like the Defendants. Indeed, on information and belief, each
18 Defendant experienced a material increase in sales, revenue, and profits from the unlawful conduct
19 described above.

20 **I. The Statutes of Limitations Are Tolloed and Defendants Are Estopped from**
21 **Asserting Statutes of Limitations As Defenses**

22 313. Defendants' conduct has continued from the early 1990s through today and remains
23 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
24 continuous injury. The damages have not occurred all at once but have continued to occur and have
25 increased as time progresses. The tort is not completed nor have all the damages been incurred until
26 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
27 public nuisance remains unabated.

28 314. Defendants are equitably estopped from relying upon a statute of limitations defense

1 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
2 assure the public that they were undertaking efforts to comply with their obligations under the
3 controlled substances laws, all with the goal of continuing to generate profits.

4 315. For example, a Cardinal Health executive claimed that it uses “advanced analytics”
5 to monitor its supply chain, and assured the public it was being “as effective and efficient as
6 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

7 316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
8 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
9 curbing the opioid epidemic in our country.”⁸⁷

10 317. Defendants, through their trade associations, filed an amicus brief that represented
11 that Defendants took their duties seriously, complied with their statutory and regulatory
12 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

13 318. Defendants purposely concealed their wrongful conduct, including by assuring the
14 public and governmental authorities that they were complying with their obligations and were
15 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
16 behavior by providing the public with false information about opioids and have continued to use
17 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
18 is continuing to this day.

19 319. Defendants have also concealed and prevented discovery of information, including
20 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
21

22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
24 [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[7b6c1998b7a0_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html) (last accessed December 21, 2017)

25 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
Opioid Abuse, Wash. Post, (Dec. 22, 2016), available at
26 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html)
[industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html) (last accessed December 21,
27 2017).

28 ⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

1 and illegal activities.

2 320. Defendants also lobbied Congress and actively attempted to halt DEA investigations
3 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
4 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a
5 distributor's license was raised.

6 321. In addition, the Defendants fraudulently attempted to convince the public that they
7 were complying with their legal obligations and working to curb the opioid epidemic.

8 322. Because the Defendants concealed the facts surrounding the opioid epidemic,
9 Westminster did not know if the existence or scope of the Defendants' misconduct, and could not
10 have acquired such knowledge earlier through the exercise of reasonable diligence.

11 323. Defendants intended that their false statements and omissions be relied upon,
12 including by Westminster, and its residents.

13 324. Defendants knew of their wrongful acts and had material information pertinent to
14 their discovery, but concealed that information from the public, including Westminster, and its
15 residents. Only Defendants knew of their widespread misinformation campaign and of their
16 repeated, intentional failures to prevent opioid diversion.

17 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
18 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
19 opioid crisis have only recently come to light.

20 326. Defendants had actual knowledge that their conduct was deceptive, and they
21 intended it to be deceptive.

22 327. Westminster was unable to obtain vital information regarding these claims absent
23 any fault or lack of diligence on Westminster's part.

24 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

25 **A. The Marketing Scheme**

26 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
27

28 ⁸⁹ See Higham and Bernstein, *supra* note 53.

1 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
 2 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
 3 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
 4 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
 5 long-term, chronic pain. Through their personal relationships, the members of this marketing
 6 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
 7 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
 8 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

9 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
 10 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
 11 made misleading statements and misrepresentations about opioids that downplayed the risk of
 12 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
 13 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
 14 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
 15 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
 16 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
 17 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
 18 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
 19 formulations provide a solution to opioid abuse.

20 330. The marketing scheme devised, implemented and conducted by the Manufacturer
 21 Defendants was designed to ensure that they unlawfully increased their sales and profits through
 22 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
 23 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
 24 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
 25 network as described above.

26 331. There was regular communication between the Manufacturer Defendants, Front
 27 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
 28 exchanged. Typically, the coordination, communication and payment occurred, and continues to

1 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
2 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
3 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
4 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
5 each agreed and took actions to hide the scheme and continue its existence.

6 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'
7 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
8 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
9 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
10 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
11 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
12 their members and constituents. By failing to disclose this information, Front Groups perpetuated
13 the marketing scheme, and reaped substantial benefits.

14 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
15 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
16 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
17 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
18 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
19 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
20 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
21 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
22 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
23 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
24 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
25 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

26 334. As public scrutiny and media coverage focused on how opioids ravaged
27 communities in California and throughout the United States, the Front Groups and KOLS did not
28 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous

1 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
2 using opioids for chronic pain.

3 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
4 categories of activities in furtherance of the marketing scheme. As described herein, the
5 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
6 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
7 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
8 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
9 and (d) efforts to limit prescriber accountability.

10 336. In addition to disseminating misrepresentations about the risks and benefits of
11 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
12 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
13 criticized or undermined the CDC Guidelines which represented "an important step – and perhaps
14 the first major step from the federal government - toward limiting opioid prescriptions for chronic
15 pain."

16 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
17 the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not
18 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
19 of the individuals who participated in the construction of these guidelines."

20 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
21 president, stating "that the CDC guideline makes disproportionately strong recommendations based
22 upon a narrowly selected portion of the available clinical evidence."

23 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
24 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
25 "neutral" and more "scientific" than the Manufacturer Defendants themselves. Without the work
26 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
27 scheme could not have achieved its common purpose.

28 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to

1 be prescribed and used for chronic pain throughout Westminster, and the epidemic continues to
2 injure Plaintiff, and consume the resources of Plaintiff's emergency health services and law
3 enforcement systems.

4 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
5 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
6 in the object of the scheme, and functioned within a structure designed to effectuate the scheme's
7 purpose.

8 **B. The Distribution Scheme**

9 342. Faced with the reality that they will now be held accountable for the consequences
10 of the opioid epidemic they created, members of the industry resort to "a categorical denial of any
11 criminal behavior or intent."⁹⁰ Defendants' actions went far beyond what could be considered
12 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
13 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
14 competitive, with the common purpose and achievement of vastly increasing their respective profits
15 and revenues by exponentially expanding a market that the law intended to restrict.

16 343. Knowing that dangerous drugs have a limited place in our society, and that their
17 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
18 and addiction causes to individuals, society and governments, California enacted California
19 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
20 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
21 to detect and report such activity.

22 344. If morality and the law did not suffice, competition dictates that the Distributor
23 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
24 if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior
25 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

1 dictates that it would do so.

2 345. The Distributor Defendants' scheme required the participation of all. If any one
3 member broke rank, its compliance activities would highlight deficiencies of the others, and the
4 artificially high quotas they maintained through their scheme would crumble. But, if all the
5 members of the enterprise conducted themselves in the same manner, it would be difficult for state
6 authorities or the DEA to go after any one of them. Accordingly, through the connections they
7 made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the
8 Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly,
9 in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting
10 Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the
11 Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance
12 Guidelines, which recognize these Defendants' duties under the law, as illustrated by the
13 subsequent industry-wide enforcement actions and consent orders issued after that time, none of
14 them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult
15 to find the right balance between proactive anti-diversion efforts while not inadvertently limiting
16 access to appropriately prescribed and dispensed medications." Yet, the Distributor Defendants
17 apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure
18 the largest possible financial return.

19 346. As described above, at all relevant times, the Distributor Defendants conspired
20 together for the purpose of unlawfully increasing sales, revenues and profits. In support of this
21 common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard
22 their statutory duties to identify, investigate, halt and report suspicious orders of opioids and
23 diversion of their drugs into the illicit market so that those orders would not result in a decrease, or
24 prevent an increase in, the necessary quotas.

25 347. At all relevant times, as described above, the Distributor Defendants exerted control
26 over, conducted and/or participated in distribution scheme by fraudulently claiming that they were
27 complying with their duties under California law to report suspicious orders and to maintain
28 systems to detect and report such activity.

348. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators' ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the "Ensuring Patient Access and Effective Drug Enforcement Act."⁹¹

349. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

350. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

351. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what

⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 doctors wanted to believe – namely, that opioids represented a means of relieving their patients’
2 suffering and of practicing medicine more compassionately.

3 352. Each Defendant’s conduct and role in creating or assisting in the creation of the
4 public health crisis now plaguing California is directly relevant to the amount of the civil penalties
5 to be awarded under California Business & Professions Code § 17536.

6 353. As a members of the boards of various Purdue entities, the Sacklers oversaw all
7 aspects of Purdue’s marketing and promotion of opioid products. As board members who were
8 personally active in directing Purdue’s operations, the Sackler Defendants knew, or should have
9 known, of Purdue’s deceptive marketing tactics of opioid products.

10 354. The Sackler Defendants also were aware of specific examples of deceptive
11 marketing through receipt of call note reviews in their capacities as board members. On information
12 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
13 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
14 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

15 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
16 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
17 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
18 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

19 356. By 2006, prosecutors at the United States Department of Justice found damning
20 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
21 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
22 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
23 events and side effects than other pain medications.

24 357. As members of the family that owns Purdue, the Sackler Defendants personally
25 benefitted from the success of OxyContin. At various points, as directors, they approved the
26 distribution of funds from Purdue to shareholders, including themselves and their extended family.

27 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
28 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.

1 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
2 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
3 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
4 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
5 the opioid related liabilities of the companies from which they were transferred.

6 359. Plaintiff is informed and believes that due to the billions of dollars in profits that
7 have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to
8 satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced
9 litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the
10 Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly
11 profited and received the benefits of that wrongdoing.

12 **VII. CAUSES OF ACTION**

13 **FIRST CAUSE OF ACTION**

14 **(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)**

15 360. Plaintiff realleges and incorporates herein by reference each and every allegation in
16 paragraphs 1 through 359 above as if set forth fully herein.

17 361. California Civil Code § 3479 provides that “anything which is injurious to health ...
18 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
19 interfere with the comfortable enjoyment of life or property ... is a nuisance.”

20 362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at
21 the same time an entire community or neighborhood, or any considerable number of persons,
22 although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

23 363. California Civil Code § 3490 states that “no lapse of time can legalize a public
24 nuisance, amounting to an actual obstruction of public right.”

25 364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought
26 by Westminster to abate the public nuisance created by the Defendants.

27 365. Each Defendant, acting individually and in concert, has created or assisted in the
28 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment

1 of life and property of entire communities or neighborhoods or of any considerable number of
2 persons in Westminster in violation of California Civil Code §§ 3479 and 3480.

3 366. The public nuisance is substantial and unreasonable. Defendants' actions caused and
4 continue to cause the public health epidemic described above in Westminster, and that harm
5 outweighs any offsetting benefit.

6 367. Defendants knew and should have known that their promotion and distribution of
7 opioids was false and misleading and that their deceptive marketing scheme would create or assist
8 in the creation of the public nuisance—i.e., the opioid epidemic.

9 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
10 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
11 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
12 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
13 so widespread, and the opioid epidemic that now exists would have been averted or much less
14 severe.

15 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
16 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
17 can be abated.

18 370. Each Defendant is liable for public nuisance because its conduct at issue is
19 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
20 endangers the safety, health, morals, comfort, or repose of a considerable number of people in
21 Westminster. Defendants' conduct is also indecent or offensive to the senses, and constitutes an
22 obstruction to the free use of property sufficient to constitute an interference with the people of
23 Westminster's comfortable enjoyment of life or property.

24 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
25 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
26 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
27 unreasonable interference with Westminster and its residents' public rights, including, but not
28 limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to

1 be free from disturbance and reasonable apprehension of danger to person or property.

2 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
3 interfered with Westminster and its residents' public rights by, *inter alia*, engaging in a promotion
4 and marketing scheme that pushed the use of opioids for indications not federally approved, and by
5 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
6 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
7 Defendants failed to comply with federal law.

8 373. Defendants have also unlawfully and intentionally distributed opioids or caused
9 opioids to be distributed within and without Westminster absent effective controls against
10 diversion. Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures
11 to maintain effective controls against diversion include Defendants' failure to effectively monitor
12 for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

13 374. Defendant's unreasonable interference with Westminster residents' public rights
14 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
15 expenditures to combat and address these harms. These damages have been suffered and continue
16 to be suffered directly by Westminster and its residents.

17 375. Defendants' actions have also created a palpable climate of fear, distress,
18 dysfunction and chaos among residents of Westminster where opioid diversion, abuse, and
19 addiction are prevalent and where diverted opioids are used frequently. Specifically, Defendants
20 conduct has caused, among other things, (a) routine separation of children from their parents who
21 have fallen victim to easy access to opioids and/or related crime; (b) children to have easy access
22 and to become addicted to opioids; (c) residents to endure both the emotional and financial costs of
23 caring for loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of
24 public spaces and property; (e) property crimes throughout Westminster; (f) employers to lose the
25 value of productive and healthy employees; (g) increased public health and safety costs; (h) a
26 reduction in potential property values within Westminster; (i) harm to families and their residential
27 neighborhoods and peaceful enjoyment of their properties due to the influx of people suffering from
28 addiction caused by Defendants' misconduct; and (j) a decrease in tax revenues for Westminster.

1 376. The impact of Defendants' conduct on Westminster is of a continuing nature.
2 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

3 377. Defendants knew or should have known that their actions would lead to the national
4 opioid epidemic and to the resulting injuries to the public rights of Westminster.

5 378. Westminster has sustained a special and peculiar injury because its damages include,
6 *inter alia*, health service expenditures, public safety expenditures, payment of opioid addiction
7 treatment, decreased tax revenues, a reduction in potential property values, residents' used and
8 enjoyment of their properties, and other costs related to opioid addiction treatment, emergency
9 medical services, and overdose prevention.

10 379. The externalized risks associated with Defendants' nuisance-creating conduct as
11 described herein greatly exceed the internalized benefits.

12 380. Defendants' actions are a direct and proximate contributing cause of the opioid
13 epidemic and the injuries to the public rights of Westminster and its residents.

14 381. Defendants, individually and collectively, are at the very least, a substantial factor
15 in causing the national opioid epidemic and of the injuries to Westminster and its residents.

16 382. The injuries to the public rights of Westminster and its residents are indivisible
17 injuries.

18 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
19 if unabated, will continue to cause an unreasonable interference with public rights of Westminster
20 and its residents.

21 384. Defendants' conduct is ongoing and persistent, and Westminster seeks all damages
22 flowing from Defendants' conduct. Westminster seeks economic losses (direct, incidental, and/or
23 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
24 above. Westminster does not seek damages for the wrongful death, physical personal injury, or
25 emotional distress caused by Defendants' actions.

26 385. Pursuant to Code of Civil Procedure § 731, Westminster requests an order providing
27 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
28 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

SECOND CAUSE OF ACTION
(Fraud – Against All Defendants)

386. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 385 above as if set forth fully herein.

387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth herein

388. The Defendants made fraudulent misrepresentations and omissions of material fact. Defendants' knowing deceptions during the relevant period, more fully described in this Complaint, were intended to induce reliance.

389. Those misrepresentations and omissions were known to be untrue by the Defendants, or were recklessly made.

390. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the dangers of abuse, and the risks of addiction.

391. As alleged herein, Defendants made false statements and/or omissions regarding their compliance with state law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements. Defendants also failed to disclose the prevalence of diversion of controlled substances, including opioids, within Westminster.

392. Defendants made those misrepresentations and omissions in an intentional effort to deceive Westminster and its residents, despite the Defendants' knowledge of the dangers of such use of prescription opioids.

393. In addition and independently, Defendants had a duty not to deceive Plaintiff because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

394. The Defendants continued making those misrepresentations, and failed to correct those material omissions, despite repeated regulatory settlements and publications demonstrating the false and misleading nature of the Defendants' omissions and/or claims.

1 395. While Defendants had a duty to disclose the above-referenced material facts, they
2 nevertheless concealed them. These false representations and concealed facts were material to the
3 conduct and actions at issue. Defendants made these false representations and concealed facts with
4 knowledge of the falsity of their representations and did so with the intent of misleading
5 Westminster, its residents, the public, and persons on whom these entities relied.

6 396. Defendants intended and had reason to expect under the operative circumstances
7 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
8 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
9 and that these entities would act or fail to act in reasonable reliance thereon.

10 397. Westminster, its residents, and others, did in fact rightfully, reasonably, and
11 justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

12 398. For instance, doctors, including those serving Westminster and its residents, relied
13 on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
14 Patients, including residents of Westminster, relied on the Defendants' misrepresentations and
15 omissions in taking prescription opioids for chronic pain relief.

16 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
17 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
18 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
19 effective response to the opioid crisis.

20 400. Defendants' misconduct alleged in this case is ongoing and persistent.

21 401. Westminster has experienced an unprecedented opioid addiction and overdose
22 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
23 services, and lost productivity to Westminster's workforce.

24 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
25 result of Defendants' fraudulent conduct.

26 403. As a direct and foreseeable consequence of Defendants' fraud, Westminster has
27 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
28 opioid addiction treatment and its secondary consequences in excess of those Westminster would

1 have otherwise incurred.

2 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
3 fraudulent, entitling Westminster to punitive damages.

4 **THIRD CAUSE OF ACTION**
5 **(Negligence – Against All Defendants)**

6 405. Plaintiff realleges and incorporates herein by reference each and every allegation in
7 paragraphs 1 through 404 above as if set forth fully herein.

8 406. To establish actionable negligence in California, Plaintiff must show a duty, a breach
9 of that duty, and injury resulting proximately therefrom.

10 407. Defendants have a duty to exercise reasonable care under the circumstances, in light
11 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
12 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
13 and still have, a duty to exercise reasonable care to prevent the threatened harm.

14 408. In addition, Defendants had a duty not to breach the standard of care established
15 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
16 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
17 to abuse, and to develop and maintain systems to detect and report such activity.

18 409. Defendants voluntarily undertook a legal duty to prevent the diversion of
19 prescription opioids by engaging in the distribution of prescription opioids and by making public
20 promises to prevent the diversion of prescription opioids.

21 410. Defendants knew of the serious problem posed by prescription opioid diversion and
22 were under a legal obligation to take reasonable steps to prevent diversion.

23 411. Defendants knew of the highly addictive nature of prescription opioids and of the
24 high likelihood of foreseeable harm to patients and communities, including Westminster, from
25 prescription opioid diversion.

26 412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
27 in accordance with applicable standards of conduct in advertising, marketing, selling, and
28 distributing opioid products in a safe manner to minimize the risk of addiction in patients and

1 resultant harm to those patients, their families and their communities, and to taxpayers and
2 municipal government such as Westminster which must incur enormous expenditures for
3 prevention, treatment, emergency response and law enforcement costs and other foreseeable costs
4 related to the need to address the consequences of a large number of residents that become addicted
5 to opioids as a result of Defendants' conduct.

6 413. As described throughout the Complaint, Defendants breached their duties to
7 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
8 monitor for, failing to report, and filling highly suspicious orders time and again.

9 414. As described throughout the Complaint, in language expressly incorporated herein,
10 Defendants misrepresented their compliance with their duties under the law and concealed their
11 noncompliance and shipments of suspicious orders of opioids to Westminster and destinations from
12 which they knew opioids were likely to be diverted into Westminster, in addition to other
13 misrepresentations alleged and incorporated herein.

14 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
15 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
16 purported benefits of long-term use of opioids for the treatment of chronic pain.

17 416. Manufacturer Defendants knew or should have known, that their affirmative
18 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
19 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
20 representatives, and internal documents, should have put them on notice that such harm was not
21 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
22 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
23 and the public.

24 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
25 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

26 418. Defendants' misconduct alleged in this case is ongoing and persistent.

27 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
28 acted with a conscious disregard for the rights and safety of other persons, and said actions had a

1 great probability of causing substantial harm.

2 420. As is described throughout this Complaint, Defendants acted without even slight
3 diligence or scant care, and with indifference, and were negligent in a very high degree,
4 disregarding the rights and safety of other persons, and said actions have a great probability of
5 causing substantial harm.

6 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
7 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
8 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
9 minimize the risk of addiction in patients and resultant harm to those patients, their families and
10 their communities, and to taxpayers and municipal government such as Westminster, including, but
11 not limited to, the following:

- 12 a. Foreseeability of harm to Westminster: Defendants were aware or reasonably
13 should have been aware of the risk of addiction of a large number of patients in
14 places such as Westminster, and need for their care and treatment and in
15 handling other consequences of their addiction and that such costs would be
16 borne by local governments such as Westminster;
- 17 b. Degree of certainty Westminster suffered harm: Westminster has suffered
18 enormous harm and costs in addressing treatment of addicted patients, including
19 but not limited to expenditures for prevention, treatment, emergency response
20 and law enforcement costs and other foreseeable costs related to the need to
21 address the consequences of a large number of residents that become addicted
22 to opioids as a result of Defendants' conduct;
- 23 c. Closeness of connection between Westminster's harm: The explosion of opioid
24 addiction and the presence of opioid addicted patients in Westminster as a result
25 of Defendants' conduct has resulted in expenditures directly for prevention,
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1 treatment, emergency response and law enforcement costs and other foreseeable
2 costs related to the need to address the consequences;

3 d. Moral blame attached to Defendants' conduct: Defendants' knew or should have
4 known that their wrongful conduct, actions and omissions would result in an
5 explosion of patients who would become addicted to opioids, and that a vast
6 opioid epidemic would result from the prescription of opioids to tens of millions
7 of patients nationwide, including within Westminster, and that the costs would
8 be borne by the state, county and municipal local governments, while
9 Defendants profited tens of billions of dollars collectively from the widespread
10 use of prescription opioid products;

11 e. Policy of preventing future harm: As a direct and foreseeable result of
12 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
13 to occur on a vast scale both nationally and locally in places such as Westminster
14 resulting in tremendous harm and cost to the patients, their families and the
15 communities in dealing with this epidemic and crisis, and there is a need to
16 ensure that the costs of such wrongful conduct is borne by Defendants so that
17 parties contemplating such or similar conduct in the future know they will be
18 held responsible for such harm;

19 f. Extent of burden to Defendants: There is no burden to Defendants in that state
20 and other law precludes them from engaging in the conduct alleged herein, and
21 there is no burden from precluding Defendants from profiting from their
22 wrongful conduct and operating within the confines of the law in advertising,
23 marketing, selling and distributing opioid products in a safe manner to minimize
24 the risk of addiction in patients and resultant harm to those patients, their
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families and their communities, and to taxpayers and municipal government such as Plaintiff Westminster; and

g. Consequences to the community of imposing a duty to exercise care with resulting liability for breach: Imposing a duty to not engage in Defendants' wrongful conduct of advertising, marketing, selling and distributing opioid products in an unsafe manner would minimize the risk of addiction in patients, and liability for a breach of this duty would benefit communities such as Westminster in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the country and the nation.

422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled substances laws cited above.

423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for security services, emergency, health, prosecution, corrections, and rehabilitation services, as well as the cost of opioid addiction treatment paid by Westminster.

424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

425. Defendants' breaches of their duty of care foreseeably and proximately caused damage to Westminster and its residents.

426. Manufacturer Defendants are guilty of negligence per se in that the Defendants violated applicable California laws, statutes, and regulations, in the manner in which they advertised, marketed, sold and distributed opioid products.

427. Distributor Defendants are guilty of negligence per se in that the Defendants violated California laws, statutes, and regulations designed to protect Plaintiff from the harms it has suffered including but not limited to the following:

- a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110390;
- b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110395;
- c. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;
- d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;
- e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and
- f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Westminster. Westminster, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

1 429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
2 fraudulent, entitling Westminster to punitive damages.

3 **FOURTH CAUSE OF ACTION**
4 **(Unjust Enrichment – Against All Defendants)**

5 430. Plaintiff realleges and incorporates herein by reference each and every allegation in
6 paragraphs 1 through 429 above as if set forth fully herein.

7 431. As an expected and intended result of their conscious wrongdoing as set forth in this
8 Complaint, Defendants have profited and benefited from the increase in the distribution and
9 purchase of opioids within Westminster, including from opioids foreseeably and deliberately
10 diverted within and into Westminster.

11 432. Plaintiff has expended substantial amounts of money in an effort to remedy or
12 mitigate the societal harms caused by Defendants' conduct.

13 433. These expenditures include, but are not limited to, the provision of emergency
14 medical services and treatment services to people who use opioids.

15 434. These expenditures have helped sustain Defendants' businesses.

16 435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
17 externalities: the cost of the harms caused by Defendants' improper distribution practices.

18 436. Defendants were aware of these obvious benefits, and their retention of the benefit
19 is unjust.

20 437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
21 benefited from those payments because they allowed them to continue providing customers with a
22 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
23 Defendants obtained enrichment they would not otherwise have obtained. Because of their
24 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
25 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
26 lacks a remedy provided by law.

27 438. Defendants' misconduct alleged in this case is ongoing and persistent.

28 439. Defendants have unjustly retained benefits to the detriment of Westminster, and

1 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
2 good conscience.

3 440. Westminster is entitled to restitution and disgorgement from Defendants in an
4 amount to be determined at trial.

5 **FIFTH CAUSE OF ACTION**
6 **(Civil Conspiracy – Against All Defendants)**

7 441. Plaintiff realleges and incorporates herein by reference each and every allegation in
8 paragraphs 1 through 440 above as if set forth fully herein.

9 442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
10 and/or distribution of opioids into California and Westminster.

11 443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
12 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
13 and Westminster.

14 444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
15 report, and prevent suspicious orders of opioids.

16 445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
17 conspiracy by increasing the volume of opioid sales in the United States through creating a market
18 for non-medical use of opioids of epidemic proportions.

19 446. Many of the Manufacturing Defendants are members, participants, and/or sponsors
20 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
21 the HDA to give further assistance to the conspiracy.

22 447. The Manufacturing Defendants hid from the general public and suppressed and/or
23 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
24 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
25 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

26 448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
27 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
28 to commit acts of fraud.

1 449. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had
2 to agree to implement similar tactics.

3 450. By intentionally refusing to report and halt suspicious orders of their prescription
4 opioids, Defendants engaged in a fraudulent scheme.

5 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
6 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
7 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
8 and were actually being diverted into the market of non-medical use.

9 452. Defendants further unlawfully marketed opioids in California and Westminster in
10 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
11 dissemination of false and misleading information about the safety and efficacy of long-term opioid
12 use through, among other things: (a) the use of "Front Groups" that appeared to be independent of
13 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
14 continuing medical education ("CME") programs controlled and/or funded by the Defendants; (d)
15 hiring and deploying so-called "key opinion leaders" or "KOLs" who were paid by the Defendants
16 to promote their message; and (e) the "detailing" activities of the Defendants' sales forces, which
17 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
18 physicians lacking the expertise of pain care specialists.

19 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
20 unbiased, independent patient-advocacy and professional organizations in order to disseminate
21 patient education materials, a body of biased and unsupported scientific "literature," and "treatment
22 guidelines" that promoted the Defendants' false messages.

23 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
24 influence prescribers' habits by promoting the Defendants' false message through, among other
25 things, writing favorable journal articles and delivering supportive CMEs as if they were
26 independent medical professionals, thereby further obscuring the Defendants' role in the
27 conspiracy.

28 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to

1 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
2 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
3 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
4 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
5 were industry-friendly and would work together with the Defendants to advance the conspiracy.

6 456. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this
7 Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes.
8 Such allegations are specifically incorporated herein.

9 457. Defendants acted with a common understanding or design to commit unlawful acts,
10 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
11 proximately caused the injuries alleged herein.

12 458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
13 reasonable or lawful excuse.

14 459. Defendants conduct in furtherance of the conspiracy described herein was not mere
15 parallel conduct because each Defendant acted directly against their commercial interests in not
16 reporting the unlawful distribution practices of their competitors to the authorities, which they had
17 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
18 actual or tacit agreement between the Defendants that they would not report each other to the
19 authorities so they could all continue engaging in their unlawful conduct.

20 460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
21 thereof, caused the direct and foreseeable losses alleged herein.

22 461. Defendants' misconduct alleged in this case is ongoing and persistent.

23 462. As a result of Defendants' conspiracy, Westminster is entitled to compensatory
24 damages in an amount to be proved at trial.

25 463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
26 fraudulent, entitling Westminster to punitive damages.

27 **SIXTH CAUSE OF ACTION**

28 **(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

1 464. Plaintiff realleges and incorporates herein by reference each and every allegation in
2 paragraphs 1 through 463 above as if set forth fully herein.

3 465. California Business & Professions Code § 17500 makes it unlawful for a business
4 to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning
5 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
6 exercise of reasonable care should be known, to be untrue or misleading.”

7 466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
8 designed to disseminate false or misleading statements designed to promote the belief that opioid
9 drugs could safely be used in a non-addictive manner.

10 467. By way of example, Actavis’s predecessor created a patient brochure for Kadian in
11 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome
12 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

13 468. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back
14 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
15 claimed that it is “less likely if you have never had an addiction problem.”

16 469. Cephalon and Purdue sponsored research and publications that falsely and
17 deceptively stated opioids did not have “ceiling dose.”

18 470. Purdue created websites, available to the public that instructed patients to seek new
19 medical providers out if their current provider would not increase their dose.

20 471. Defendants’ false and deceptive advertising practices resulted in increased opioid
21 dosages being prescribed to Westminster’s residents, increasing the incidence of opioid addiction
22 and overdose in Westminster.

23 472. Distributor Defendants also repeatedly omitted material information and/or falsely
24 represented that they were effectively preventing diversion and were monitoring, reporting, and
25 preventing suspicious orders.

26 473. As alleged above, Defendants’ statements about the risks associated with opioid use
27 were not supported by or were contrary to the scientific evidence.

28 474. As alleged above, each Defendant’s conduct, separately and collectively, was likely

1 to deceive California payors who purchased or covered the purchase of opioids.

2 475. Westminster seeks restitution and injunctive relief under California Business &
3 Professions Code § 17535.

4 476. Westminster also seeks an order assessing a civil penalty of two thousand five
5 hundred dollars (\$2,500) against Defendants for each violation of California's False Advertising
6 Law pursuant to California Business & Professions Code § 17536.

7 **SEVENTH CAUSE OF ACTION**
8 **(Negligent Failure to Warn– Against Manufacturer Defendants)**

9 477. Plaintiff realleges and incorporates herein by reference each and every allegation in
10 paragraphs 1 through 476 above as if set forth fully herein.

11 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
12 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
13 adequately warning the medical profession about the risk of addiction from the use of opioid
14 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
15 cancel out, and render meaningless any written warnings given about the risk of addiction from the
16 use of opioid products.

17 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
18 to adequately warn the medical profession about the risk of addiction from the use of opioid
19 products, including by overpromoting and over-marketing opioid products in a manner so as to
20 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
21 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
22 products in situations and for patients who should not have been using those drugs or should have
23 used them only as a last resort before other means were used or other less addictive and dangerous
24 drugs were prescribed.

25 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
26 and overpromoting and over-marketing the use of prescription opioid products, there is now a
27 national opioid addiction epidemic, including in Westminster. The People, as a further direct and
28 proximate consequence and result thereof, sustained injuries and damages including but not limited

1 to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs,
2 law and regulatory enforcement costs, opioid disposal programs, and measures for prevention of
3 further opioid abuse and addiction.

4 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
5 fraudulent, entitling Westminster to punitive damages.

6 **EIGHTH CAUSE OF ACTION**
7 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler Defendants)**

8 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
9 paragraphs 1 through 481 above as if set forth fully herein.

10 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
11 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
12 possess a right to payment from Purdue.

13 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
14 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
15 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
16 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

17 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
18 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
19 including Plaintiff.

20 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
21 them pursuant to California Civil Code § 3439.04(a)(1).

22 **NINTH CAUSE OF ACTION**
23 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

24 487. Plaintiff realleges and incorporates herein by reference each and every allegation in
25 paragraphs 1 through 486 above as if set forth fully herein.

26 488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
27 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
28 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection

1 of its judgment against Purdue entered in this action.

2 489. After the Sackler Defendants became aware in or about 1999 that Purdue faced
3 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
4 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping
5 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
6 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
7 Defendants and their extended family.

8 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
9 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
10 to commit acts of fraud.

11 491. Purdue and the Sackler Defendants acted with a common understanding or design
12 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
13 excuse, which directly and proximately caused the injuries alleged herein.

14 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
15 unlawfully, and without a reasonable or lawful excuse.

16 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
17 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
18 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
19 judgment entered in this action.

20 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
21 compensatory damages in an amount to be proved at trial.

22 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
23 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Westminster and the People respectfully request judgment in their favor granting the following relief:

- a) Entering Judgment in favor of Westminster and the People in a final order against each of the Defendants;
- b) An award of actual and consequential damages in an amount to be determined at trial;
- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment

of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;

- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff's judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;
- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;
- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and
- v) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Dated: March 27, 2019

ROBINS KAPLAN LLP

By: 

Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT D

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment
 form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF SANTA ANA; and
(LO ESTÁ DEMANDANDO EL DEMANDANTE): THE PEOPLE OF THE
STATE OF CALIFORNIA, by and through Santa Ana City
Attorney Sonia R. Carvalho

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:

(El nombre y dirección de la corte es):

San Francisco County Superior Court
 Civic Center Courthouse
 400 McAllister Street
 San Francisco, CA 94102-4515

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783

310-552-0130 310-229-5800

Lucas A. Messenger, Bar No. 217645

ROBINS KAPLAN LLP

Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

CLERK OF THE COURT (Secretario)

Clerk, by

DE LA VEGA-NAVARRO, Rossaly, Deputy
 (Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):
3. ☐ on behalf of (specify):

- under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other (specify):

4. ☐ by personal delivery on (date):

[SEAL]

SUM-200(A)

SHORT TITLE: City of Santa, et al. v. Purdue Phara
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

COPY



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Attorneys for Plaintiffs City of Santa Ana and The
People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

CITY OF SANTA ANA; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Santa Ana
City Attorney Sonia R. Carvalho,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

Case No.

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;
8. FRAUDULENT TRANSFER; and

ENDORSED
FILED
Superior Court of California
County of San Francisco
MAR 28 2019
CLERK OF THE COURT
BY: ROSSALY DE LA VEGA
Deputy Clerk

CGC - 19 - 574872

1 SACKLER, an individual; IRENE
 2 SACKLER LEFCOURT, an individual;
 3 BEVERLY SACKLER, an individual and
 4 as trustee for TRUST FOR THE BENEFIT
 5 OF MEMBERS OF THE RAYMOND
 6 SACKLER FAMILY; THERESA
 7 SACKLER, an individual; DAVID A.
 8 SACKLER, an individual; CEPHALON,
 9 INC.; TEVA PHARMACEUTICAL
 10 INDUSTRIES, LTD.; TEVA
 11 PHARMACEUTICALS USA, INC.;
 12 JANSSEN PHARMACEUTICALS, INC.;
 13 JOHNSON & JOHNSON; ORTHO-
 14 MCNEIL-JANSSEN
 15 PHARMACEUTICALS, INC.; JANSSEN
 16 PHARMACEUTICA, INC.; ENDO
 17 HEALTH SOLUTIONS INC.; ENDO
 18 PHARMACEUTICALS INC.; ACTAVIS
 19 PLC; WATSON PHARMACEUTICALS,
 20 INC.; WATSON LABORATORIES, INC.;
 21 ACTAVIS PHARMA, INC.; ACTAVIS
 22 LLC; ALLERGAN PLC; ALLERGAN,
 23 INC.; ALLERGAN USA, INC.; INSYS
 24 THERAPEUTICS, INC.;
 25 MALLINCKRODT, PLC;
 26 MALLINCKRODT, LLC; CARDINAL
 27 HEALTH, INC.;
 28 AMERISOURCEBERGEN
 CORPORATION; MCKESSON
 CORPORATION; and
 DOES 1-100, inclusive,

Defendants.

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Santa Ana Through Illicit Channels.....	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Santa Ana Through Illicit Channels	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Santa Ana	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff City of Santa Ana (hereinafter, “Santa Ana”) has been particularly hard hit, causing Santa Ana to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. Santa Ana, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of Santa Ana (the “People,” and together with Santa Ana, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants' efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. Santa Ana has seen increased costs of, among other things, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (e) public safety connected to the opioid epidemic within Santa Ana, including police, emergency

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 response services, and detention centers; (f) increased burden on Santa Ana's code enforcement
2 programs; (g) re-education of doctors and patients about the appropriate use of opioids; and (h)
3 extensive clean-up of public parks, spaces, and facilities. At the same time, Santa Ana has seen a
4 reduction to tax revenues caused by the epidemic created by the Defendants. Almost every citizen
5 of Santa Ana has been affected. The resulting damage to Santa Ana was directly and foreseeably
6 caused by Defendants' actions.

7 7. These increased costs could have been—and should have been—prevented by the
8 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
9 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
10 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
11 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
12 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
13 protecting opioids from theft, misuse, and diversion.

14 8. Instead of acting with reasonable care and in compliance with their legal duties,
15 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
16 process.

17 9. At the same time, Defendants flooded the market with false statements designed to
18 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
19 claims were false.³

20 10. Defendants' actions have not only caused significant costs, but have also created a
21 palpable climate of fear, distress, dysfunction and chaos among Santa Ana residents where opioid
22 diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

23 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
24 and/or unlawful conduct.

25
26
27
28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. Santa Ana, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. Santa Ana has standing to recover damage incurred because of Defendants' actions and omissions. Santa Ana has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical’s products and Janssen’s profits inure to J&J’s benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as “Actavis”).

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

1 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
2 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
3 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
4 California with the California Secretary of State.

5 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
6 principal place of business located in Chandler, Arizona.

7 38. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source
8 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
9 United States, including California. Subsys was indicated by the FDA for the treatment of
10 breakthrough cancer pain that other opioids could not eliminate.

11 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
12 bribe physicians with purported speaking fees for marketing and education events in exchange for
13 them prescribing Subsys for off-label uses. Insys’ founder and several other former Insys executives
14 were recently indicted by federal prosecutors on racketeering charges, alleging that these
15 individuals approved and fostered fraudulent behavior against insurance companies and also
16 conspired to bribe practitioners in various states. Insys Group is registered to do business in
17 California with the California Secretary of State.

18 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
19 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
20 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
21 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
22 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

23 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
24 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
25 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
26 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
27 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
28 Products are registered to do business in California with the California Secretary of State.

42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and Mallinckrodt are the “Manufacturer Defendants.”

C. The Distributor Defendants

43. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

44. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with Santa Ana and its residents, and has purposefully availed itself of the advantages of conducting business with and within Santa Ana. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

45. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

46. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with Santa Ana and its residents, and has purposefully availed itself of the advantages of conducting business with and within Santa Ana. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

48. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with Santa Ana and its residents, and has purposefully availed itself of the advantages of conducting business with and within Santa Ana. McKesson is in the chain of distribution of prescription opioids. McKesson

1 Corporation is registered to do business in California with the California Secretary of State.

2 49. The data which reveals and/or confirms the identity of the other wrongful opioid
3 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
4 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
5 voluntarily disclose the data necessary to identify with specificity the transactions which will form
6 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

7 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
8 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
9 listed on the New York Stock Exchange and their principal business consists of the nationwide
10 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
11 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
12 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
13 suspicious orders. Santa Ana has reason to believe each has engaged in unlawful conduct which
14 resulted in the distribution, dispensing, and diversion of prescription opioids into Santa Ana. Santa
15 Ana names each of the "Big 3" herein as defendants and places the industry on notice that Santa
16 Ana is acting to abate the public nuisance plaguing its community. Distributor Defendants have
17 had substantial contacts and business relationships with the People of Santa Ana. Distributor
18 Defendants have purposefully availed themselves of business opportunities within Santa Ana.

19 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
20 Defendants."

21 **D. The Doe Defendants**

22 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
23 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
24 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
25 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
26 is informed and believes, and on such information and belief alleges, that each of the Defendants
27 named as a DOE is responsible in some manner for the events and occurrences alleged in this
28 Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

53. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance in Santa Ana, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

54. Venue is proper in this Court because Defendants transact business in California and San Francisco County, and some of the acts complained of occurred in this venue. Furthermore, Defendant Distributor McKesson's principal place of business is in San Francisco County, and McKesson conducted business and continues to do business throughout the United States and in the State of California by regularly and continuously distributing prescription opioids throughout the State of California.

IV. GENERAL FACTUAL ALLEGATIONS**A. An Overview of the Opioid Epidemic**

55. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death."⁵

56. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

57. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

1 director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have
2 very, very high inherent risks . . . and there's no such thing as a fully safe opioid."⁶

3 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
4 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
5 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

6 59. Before the 1990s, generally accepted standards of medical practice dictated that
7 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
8 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
9 patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as
10 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
11 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
12 generally did not prescribe opioids for chronic pain.

13 60. The market for chronic pain patients, however, was much larger, and to take
14 advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for
15 chronic pain.⁷

16 61. As described herein, Defendants engaged in conduct that directly caused doctors to
17 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
18 obligations to prevent diversion of the highly addictive substance.

19 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
20 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
21 for every person in the United States to have a bottle of pills. This represents an increase of 300%
22 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
23 were dispensed per 100 persons.

24 63. Many Americans, including Californians and residents of Santa Ana, are now
25

26 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

27 ⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times
28 (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United
 2 States, an increase of more than 22 percent over the previous year. The New York Times reported
 3 in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly
 4 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 5 a public health emergency by the President of the United States. The wave of opioid addiction was
 6 created by the increase in prescriptions.

7 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 8 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 9 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 10 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 11 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 12 80 percent of people who use heroin first misused prescription opioids.

13 65. Drug overdose deaths among all Americans increased more than 200 percent
 14 between 1999 and 2015.

15 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 16 there were 4,654 total opioid overdose deaths in 2016.⁹

17 ///

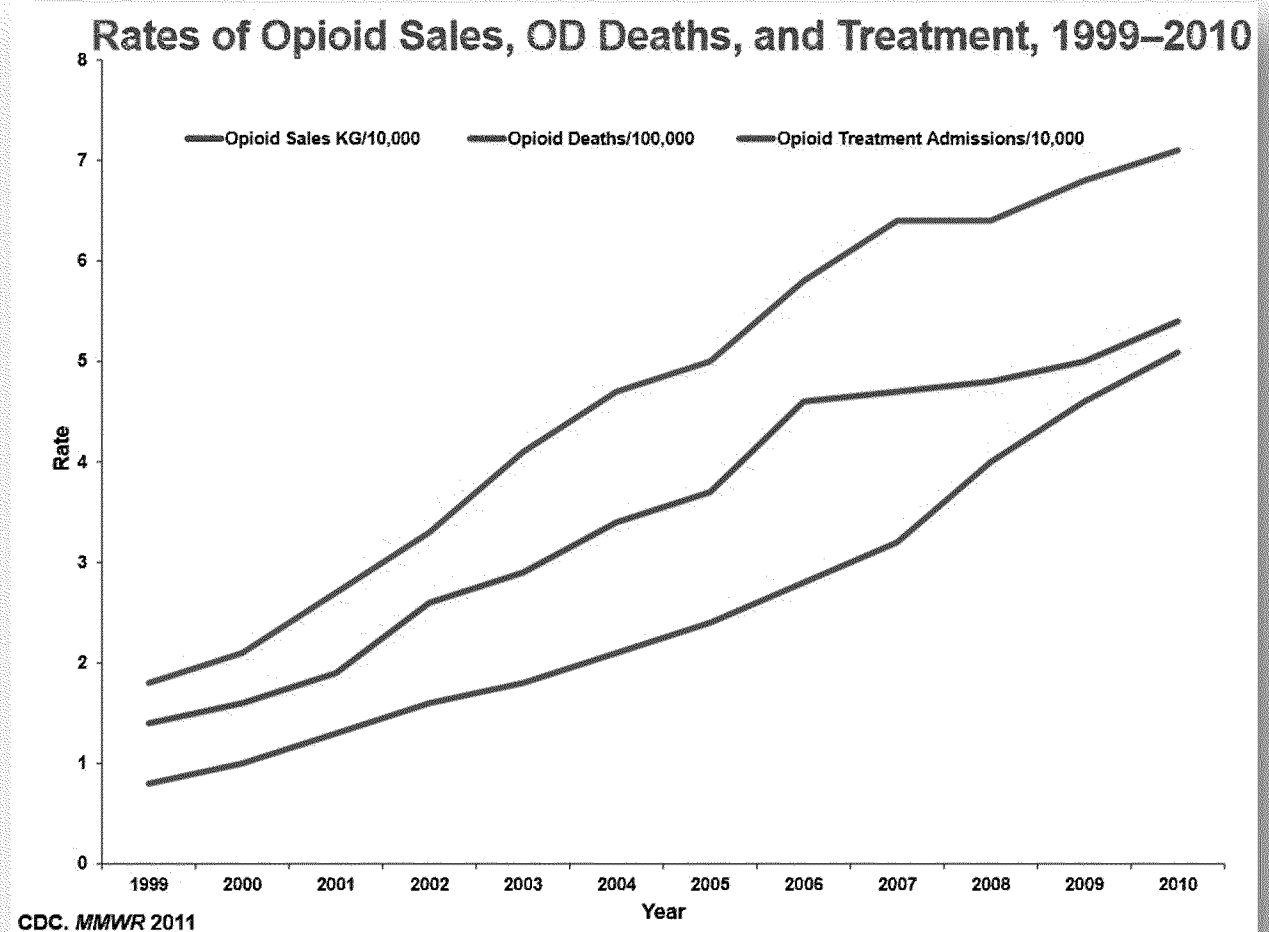
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26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*, N.Y.
 27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, *California Opioid Summary*, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in Santa Ana, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants’ messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
2 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
3 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
4 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
5 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
6 carried a low, or no, risk of addiction.

7 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
8 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
9 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
10 of actual addiction began appearing, and advocated that the signs of addiction should be treated
11 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
12 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
13 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
14 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
15 opioid use, including the supposed ability of opioids to improve function and quality of life, even
16 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
17 claims.

18 75. These statements were not only unsupported by or contrary to the scientific
19 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
20 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
21 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

22 76. The Manufacturer Defendants began their marketing schemes decades ago and
23 continue them today.

24 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
25 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
26 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
27
28

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
 24

25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 27 29, 2017).

28 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient
 Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 100. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
6 unbranded advertising stated that “People who take opioids as prescribed usually do not become
7 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use.”

10 101. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 104. For example, the New York Attorney General (“NY AG”) found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in Santa Ana and doctors treating residents of Santa Ana.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 _____
28 ²³ Dr. Portenoy was a member of the board of the APF.

²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 119. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 120. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 121. On information and belief, AAPM is viewed internally by Endo as “industry

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26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 122. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

26
27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in Santa Ana during the relevant time period, are still available online, and were often
 12 reprinted in the Journal of Pain, which is the official journal of the American Pain Society. The
 13 Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 126. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 128. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 129. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 130. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 131. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
25 marketing materials along with the rights to Kadian, it appears that Actavis
26 continued to use this brochure in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
28 People Living with Pain (2007), which suggests that addiction is rare and
limited to extreme cases of unauthorized dose escalations, obtaining
duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Santa Ana, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 138. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain *is under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in Santa Ana, to PartnersAgainstPain.com, which contained false and
14 misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 **Deceptive Claims of Pseudoaddiction**

22 139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
some of its proponents” and reported that despite the fact that Endo trained its sales representative
to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
Management testified to [the NY AG] that he was not aware of any research validating the
‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 141. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including Santa Ana the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

1 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
 2 widely believed by doctors to detect and deter abuse—“for improving outcomes related to
 3 overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that
 4 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
 5 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
 6 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

7 143. To underplay the risk and impact of addiction and make doctors feel more
 8 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
 9 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
 10 failed to disclose the increased difficulty of stopping opioids after long-term use.

11 144. For example, on information and belief, a 2011 non-credit educational program
 12 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
 13 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

14 145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
 15 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
 16 by gradually decreasing the dose of medication during discontinuation” without mentioning any
 17 hardships that might occur.³⁸ This publication was available on APF’s website until the
 18 organization dissolved in May 2012.

19 146. Detailers for Janssen have told and continue to tell doctors in California, including
 20 Santa Ana, that their patients would not experience withdrawal if they stopped using opioids.

21 **Deceptive Minimization of Opioid Withdrawal**

22 147. The Manufacturer Defendants also deceptively minimized the significant symptoms
 23 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
 24 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
 25 understated the difficulty of tapering, particularly after long-term opioid use.

26 148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

27
 28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

1 recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]”
 2 to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,”
 3 because “physical dependence on opioids is an expected physiologic response in patients exposed
 4 to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that
 5 “more than a few days of exposure to opioids significantly increases hazards” and “each day of
 6 unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The
 7 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years
 8 on high dosages because of physical and psychological dependence” and highlights the difficulties,
 9 including the need to carefully identify “a taper slow enough to minimize symptoms and signs of
 10 opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The
 11 CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of
 12 different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

13 **Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk**

14
 15 149. The Manufacturer Defendants also falsely claimed that doctors and patients could
 16 increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to
 17 patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer
 18 Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this
 19 misrepresentation, doctors would have abandoned treatment when patients built up tolerance and
 20 lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that
 21 were made by, and are continuing to be made by Defendants, are described below:

- 22 a. On information and belief, Actavis’s predecessor created a patient brochure for
 23 Kadian in 2007 that stated, “Over time, your body may become tolerant of
 24 your current dose. You may require a dose adjustment to get the right amount
 25 of pain relief. This is not addiction.” Upon information and belief, based on
 26 Actavis’ acquisition of its predecessor’s marketing materials along with the
 27 rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- 28 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for
 People Living with Pain* (2007), which claims that some patients “need” a
 larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in Santa Ana that they should increase the dose of OxyContin, rather
than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was **no** evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in Santa Ana, that Opana ER is harder to abuse and given demonstrations to nurse
22 practitioners about Opana ER’s purported abuse deterrent properties.

23
24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
26 [push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

27 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
28 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
[ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those statements to be false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

158. Because Orpana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.

159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse, and that its abuse deterrent properties can be defeated.

160. These statements and omissions by Purdue are false and misleading, and conflict with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 430.

27 ⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose*
 28 *epidemic*, Business Insider (Mar. 14, 2016), available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in Santa Ana, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewharper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

174. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

26 _____
27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by Santa Ana.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

26
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

28 ⁵² *Id.*

1 misrepresentations deceived and continue to deceive doctors and patients in California, including
2 in Santa Ana, about the risks and benefits of long-term opioid use. California doctors confirm this.
3 Studies also reveal that many doctors and patients are not aware of or do not understand these risks
4 and benefits. Indeed, patients often report that they were not warned they might become addicted
5 to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid
6 patients found that 4 out of 10 were not told opioids were potentially addictive. Plaintiff is informed
7 and believes that California residents were never told that they might become addicted to opioids
8 when they started taking them, were told that they could easily stop using opioids, or were told that
9 the opioids they were prescribed were less addictive than other opioids.

10 192. Numerous doctors and substance abuse counselors in California note that many of
11 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
12 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
13 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
14 for opioid addiction.

15 193. The Manufacturer Defendants knew and should have known that their
16 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
17 when they made them.

18 194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
19 properties of their opioids caused and continue to cause doctors in California, including doctors in
20 Santa Ana, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis,
21 and fibromyalgia, rather than prescribing less addictive medications. Absent Manufacturers
22 Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids
23 to as many patients, and there would not have been as many opioids available for misuse and abuse
24 or as much demand for those opioids.

25 195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
26 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
27 California, including in Santa Ana. Opioids are the most common means of treatment for chronic
28 pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per

1 year are prescribed a long-acting opioid.

2 196. In California, including Santa Ana, Manufacturer Defendants' deceptive marketing
3 of the abuse-deterrent properties of their opioids during the past few years has been particularly
4 effective. For example, one survey reports that pain specialists were more likely to recognize that
5 OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those
6 properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using
7 more of it than those who did not know it was an AD opioid. Although sales of AD opioids still
8 represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they
9 represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in
10 opioid sales revenue in 2015).

11 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 198. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 199. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 200. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 201. Diversion can occur at any point in the opioid supply chain.

4 202. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 205. Opioid diversion occurs at an alarming rate in the United States.

23 206. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 **210.** In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 211. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 212. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for Santa Ana and the people therein.

25 213. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

214. Thus, all opioid distributors are required to maintain effective controls against opioid diversion. They are required to create and use a system to identify and report to the California State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of unusually large size, orders that are disproportionate, orders that deviate from a normal pattern, and/or orders of unusual frequency. To comply with these requirements, distributors must know their customers, must conduct due diligence, must report suspicious orders, and must terminate orders if there are indications of diversion.

215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA.

216. Under the CSA, anyone authorized to handle controlled substances must track shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from the point of manufacture through distribution to the point of sale. ARCOS accumulates data on distributors' controlled substances and transactions, which are then used to identify diversion. Each person or entity registered to distribute ARCOS reportable controlled substances, including opioids, must report each acquisition and distribution transaction to the DEA. *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

217. Plaintiff does not bring causes of action based on violations of federal statutes and regulations. However, the existence of these complicated regulatory schemes shows Defendants' intimate knowledge of the dangers of diversion of prescription opioids and the existence of a thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this knowledge and longstanding regulatory guidance of how to deter and prevent diversion of prescription opioids.

1 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
 2 **Opioids to Santa Ana Through Illicit Channels**

3 218. The Distributor Defendants have been and continue to be well-aware of problems
 4 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance
 5 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
 6 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
 7 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
 8 that the DEA also provides distributors with data on controlled substance distribution patterns and
 9 trends, including data on the volume and frequency of orders and the percentage of controlled
 10 versus non-controlled purchases. The distributors are also given case studies, legal findings against
 11 other registrants, and ARCOS profiles of their customers whose previous purchases may have
 12 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
 13 Defendants should look for in order to identify potential diversion.

14 219. Since 2007, the DEA has hosted at least five conferences to provide registrants with
 15 updated information about diversion trends and regulatory changes that affect the drug supply
 16 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
 17 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
 18 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
 19 also request clarification on DEA policies, procedures, and interpretations of the CSA and
 20 implementing regulations.

21 220. Since 2008, the DEA also has participated in numerous meetings and events with
 22 the legacy Healthcare Distribution Management Association (HDMA), now known as the
 23 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
 24 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
 25 guidance to the association concerning suspicious order monitoring, and the association has
 26 published guidance documents for its members on suspicious order monitoring, reporting
 27 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
 28 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 Santa Ana and its residents. Each Distributor Defendant knew or should have known that the
7 opioids reaching Santa Ana were not being consumed for medical purposes and that the amount of
8 opioids flowing to Santa Ana was far in excess of what could be consumed for medically necessary
9 purposes.

10 232. The Distributor Defendants negligently or intentionally failed to adequately control
11 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
12 substances would have anticipated the danger of opioid diversion and protected against it by, for
13 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
14 greater oversight, security, and control of supply channels; (c) looking more closely at the
15 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
16 amounts greater than the populations in those areas would warrant; (d) investigating demographic
17 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
18 Santa Ana; (e) providing information to pharmacies and retailers about opioid diversion; and (f) in
19 general, simply following applicable statutes, regulations, professional standards, and guidance
20 from government agencies and using a little bit of common sense.

21 233. On information and belief, the Distributor Defendants made little to no effort to visit
22 the pharmacies servicing the areas around Santa Ana to perform due diligence inspections to ensure
23 that the controlled substances the Distributor Defendants had furnished were not being diverted to
24 illegal uses.

25 234. On information and belief, the compensation the Distributor Defendants provided
26 to certain of their employees was affected, in part, by the volume of their sales of opioids to
27 pharmacies and other facilities servicing the areas around Santa Ana, thus improperly creating
28 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid

1 abuse.

2 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
3 flooding the market in and around Santa Ana with highly addictive opioids would allow opioids to
4 fall into the hands of children, addicts, criminals, and other unintended users.

5 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
6 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
7 and death. It was also reasonably foreseeable that many of these injuries would be suffered by Santa
8 Ana residents, and that the costs of these injuries would be borne by Santa Ana.

9 237. The Distributor Defendants knew or should have known that the opioids being
10 diverted from their supply chains would contribute to the opioid epidemic faced by Santa Ana, and
11 would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
12 addiction, demand, illegal transactions, economic ruin, and human tragedy.

13 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
14 and around Santa Ana, but, on information and belief, they nevertheless persisted in a pattern of
15 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
16 with such frequency that they knew or should have known these commonly abused controlled
17 substances were not being prescribed and consumed for legitimate medical purposes.

18 239. The use of opioids by Santa Ana residents who were addicted or who did not have
19 a medically necessary purpose could not have occurred without the knowing cooperation,
20 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
21 Defendants adhered to effective controls to guard against diversion, Santa Ana and its residents
22 would have avoided significant injury.

23 240. The Distributor Defendants made substantial profits over the years based on the
24 diversion of opioids into Santa Ana. The Distributor Defendants knew that Santa Ana would be
25 unjustly forced to bear the costs of these injuries and damages.

26 241. The Distributor Defendants' intentional distribution of excessive amounts of
27 prescription opioids showed an intentional or reckless disregard for the safety of Santa Ana and its
28 residents. Their conduct poses a continuing threat to the health, safety, and welfare of Santa Ana.

1 242. The state laws at issue here are public safety laws.

2 243. The Distributor Defendants' violations constitute prima facie evidence of
3 negligence under state law.

4 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
5 **of Opioids to Santa Ana Through Illicit Channels**

6 244. The same legal duties to prevent diversion, and to monitor, report, and prevent
7 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
8 were also legally required of the Manufacturer Defendants under California law.

9 245. In addition to a common law duty to exercise reasonable care in the promotion and
10 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
11 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
12 determined by the Board. *See* 16 CCR 1782.

13 246. On information and belief, for over a decade the Manufacturer Defendants have
14 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
15 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
16 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
17 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
18 Manufacturer Defendants breached their duties under state law.

19 247. The Manufacturer Defendants had access to and possession of the information
20 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
21 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
22 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
23 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
24 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
25 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
26 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
27 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer
28 Defendants built receipt of this information into the payment structure for the opioids provided to

1 the opioid distributors.

2 248. The Manufacturer Defendants' actions and omission in failing to effectively prevent
3 diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful
4 diversion of opioids into Santa Ana.

5 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

6 249. As the demand for prescription opioids grew, fueled by their potency and purity,
7 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
8 traveling across state, city, and county lines in a variety of ways.

9 250. First, prescriptions written in one state would, under some circumstances, be filled
10 in a different state. But even more significantly, individuals transported opioids from one
11 jurisdiction specifically to sell them in another.

12 251. When authorities in one state cracked down on opioid suppliers, out-of-state
13 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
14 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
15 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
16 practice became so common that authorities dubbed these individuals "prescription tourists."

17 252. The facts surrounding numerous criminal prosecutions illustrate this common
18 practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught
19 flying to California in attempts to obtain additional sources of supply for their drug operation which
20 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

21 253. In another example, a man from Warren County, Ohio, who was sentenced to four
22 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
23 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
24 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a
25

26 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

27 ⁵⁹ Andrew Welsh-Huggins, Associated Press, 'Prescription Tourists' Thwart States' Crackdown on Illegal
28 *Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

1 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
2 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
3 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
4 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
5 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
6 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

7 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
8 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
9 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
10 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
11 customers were from other states.⁶³

12 255. In yet another case, defendants who operated a pill mill in south Florida within
13 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
14 transported oxycodone back to the area for both use and distribution by local drug trafficking
15 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
16 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
17 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
18 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
19 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
20

21 _____
22 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
<http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
23 accessed July 25, 2018).

24 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
25 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

26 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
27 accessed July 25, 2018).

28 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
[patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

1 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
2 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
3 Kentucky residents.”⁶⁵

4 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
5 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
6 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
7 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
8 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
9 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
10 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
11 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
12 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

13 257. While the I-75 corridor was well utilized, prescription tourists also came from other
14 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
15 mills come from as far away as Arizona and Nebraska.⁷⁰

16 258. Similar pipelines developed in other regions of the country. For example, the I-95
17 corridor was another transport route for prescription pills. As the director of the Maine Drug
18 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
19 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
20

21 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s*
24 *Deadliest Drug Epidemic* 171 (2016).

25 ⁶⁷ *Id.* at 172

26 ⁶⁸ *Id.* at 171

27 ⁶⁹ *Id.*

28 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
(last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
(last accessed July 25, 2018)

1 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
2 Ohio, and Kentucky.

3 259. Along the west coast, over a million pills were transported from the Lake Medical
4 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²
5 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
6 Everett-based dealer who received the pills from southern California wore a diamond necklace in
7 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
8 OxyContin—connecting Los Angeles and Washington state.

9 260. Defendants certainly were aware, or should have been aware, that pill mills from
10 around the country were pushing its products. Defendants purchased nationwide, regional, state,
11 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
12 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
13 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
14 compute, and track their competitors' sales, and to compare and analyze market share information.

15 261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
16 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
17 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
18 regarding competing drugs, and analyzed the market share of those drugs.

19 262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
20 rewarded sales representatives who happened to have pill mills within their territories, enticing
21 those representatives to look the other way even when their in-person visits to such clinics should
22 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
23 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
24 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
25 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric

26
27 ⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and
Heartbreak, Los Angeles Times (July 10, 2016), available at [http://www.latimes.com/projects/la-me-
oxycontin-everett/](http://www.latimes.com/projects/la-me-
oxycontin-everett/) (last accessed July 25, 2018)

28 ⁷³ *Id.*

1 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
2 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
3 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
4 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
5 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

6 ⁷⁴

7 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
8 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
9 sales representative "it was packed with a line out the door, with people who looked like gang
10 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
11 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
12 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
13 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
14 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
15 2010 to inform the authorities.

16 264. Abundant evidence, thus, establishes that prescription opioids migrated between
17 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
18 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
19 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
20 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
21 prescription opioid pills were hard to get in one area, they migrated from another. The
22 manufacturers and distributors were fully aware of this phenomenon and profited from it.

23 265. Defendants each knew or should have known that opioid diversion and abuse was
24 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide

25 _____
26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

1 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
2 allowed to continue the unlawful diversion of opioids into Santa Ana.

3 **G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the**
4 **Harm Alleged Herein and Substantial Damages**

5 266. As the Manufacturer Defendants' efforts to expand the market for opioids increased,
6 so have the rates of prescription and the sale of their products, as well as the rates of opioid-related
7 substance abuse, hospitalization, and death among Santa Ana residents and across the nation.
8 Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of
9 opioids into communities like Santa Ana, fueling the epidemic.

10 267. There is a "parallel relationship between the availability of prescription opioid
11 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
12 associated adverse outcomes."⁷⁷

13 268. Opioids are widely diverted and improperly used, and the widespread use of the
14 drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

15 269. The epidemic is "directly related to the increasingly widespread misuse of powerful
16 opioid pain medications."⁷⁹

17 270. The increased abuse of prescription opioids—along with growing sales—has
18 contributed to a large number of overdoses and deaths.

19 271. As shown above, the opioid epidemic has escalated in Santa Ana with devastating
20 effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants'
21 increased distribution of opioids.

22 272. Because of the well-established relationship between the use of prescription opioids
23 and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to Santa
24 Ana and areas from which opioids are being diverted to Santa Ana, has caused the opioid epidemic
25 to include heroin addiction, abuse, and death.

26 _____
27 ⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N.
Eng. J. Med. 241 (2015).

28 ⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Santa Ana.

274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Santa Ana.

275. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in Santa Ana.

276. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in Santa Ana. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by Santa Ana and residents of Santa Ana.

277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Santa Ana seeks relief, as alleged herein. Santa Ana also seeks the means to abate the epidemic created by the Defendants.

278. Santa Ana seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

279. Santa Ana seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

280. Santa Ana seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

281. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

282. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at <https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and->

1 283. The community-based problems require community-based solutions that have been
2 limited by budgetary constraints.

3 284. Having profited enormously through the aggressive sale, misleading promotion, and
4 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
5 financial burdens their conduct has inflicted upon Santa Ana.

6 285. The opioid epidemic still rages because the fines and suspensions imposed by the
7 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
8 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
9 registration numbers and when one facility is suspended, they simply ship from another facility.

10 286. The Defendants have abandoned their duties imposed by the law, taken advantage
11 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
12 Santa Ana.

13 287. In the course of conduct described in this Complaint, Defendants have acted with
14 oppression, fraud, and malice, both actual and presumed.

15 **H. The Impact of Opioid Abuse on Santa Ana**

16 288. Defendants' creation, through false and misleading advertising and a failure to
17 prevent diversion, of a virtually limitless opioid market has significantly harmed Santa Ana and
18 resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
19 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
20 abused come, directly or indirectly, through doctors' prescriptions.

21 289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
22 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
23 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
24 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
25 associated with the consumption of a counterfeit version of the prescription drug Norco
26 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has

27 _____
28 [effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf](https://www.cdph.ca/Programs/CID/DCDC/Pages/Effectiveness/Research/Prescription-Opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf) (last accessed
January 8, 2018).

1 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
2 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
3 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further
4 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
5 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
6 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
7 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
8 related overdoses, with 55% of those resulting from prescription opioids.

9 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
10 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
11 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
12 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
13 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

14 291. Even Santa Ana's youngest residents bear the consequences of the opioid abuse
15 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
16 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
17 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
18 Many Santa Ana women have become addicted to prescription opioids and have used these drugs
19 during their pregnancies. As a result, many Santa Ana infants suffer from opioid withdrawal and
20 Neonatal Abstinence Syndrome ("NAS").⁸⁵

21 _____
22 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
23 *year*, LA Times (Oct. 27, 2014), available at [http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html)
24 [prescription-hospital-er-20141026-story.html](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html) (last accessed December 21, 2017).

25 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
26 *The Opioid Crisis in Indian Country*, at 37, available at
27 <https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
28 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US, 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at

292. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation can cost thousands of dollars for each occurrence.

293. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

294. Many of the parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

295. Opioid addiction is now the primary reason that Californians seek substance abuse treatment, and admissions to drug treatment facilities in California more than doubled from 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one facility in northern California, up to 90% – started on legal opioid prescriptions.

296. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in California. California faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]” and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting worse.

297. There is little doubt that each Defendant's deceptive marketing and distribution scheme has precipitated this public health crisis in California, including Santa Ana, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created

<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 a population of patients physically and psychologically dependent on them (the demand). And when
2 those patients can no longer afford or legitimately obtain opioids, they often turn to the street to
3 buy prescription opioids or even heroin.

4 298. The effects of Defendants' deceptive marketing and distribution scheme has further
5 impacted Plaintiff in a foreseeable way such that Santa Ana must devote increased resources to the
6 burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For
7 example, tax dollars are required to maintain public safety of places where the addicted homeless
8 attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight
9 the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
10 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
11 *aureus* (MRSA) are spread by opioid abuse.

12 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
13 have recruited addicts nationally with false and misleading promises of the medically supervised
14 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
15 effective rehabilitation available in beautiful California communities. These for-profit
16 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
17 that many have provided substandard care including use of physicians who have had their license
18 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
19 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
20 as long as there are third party payments available, and then throw them out of the facilities to be
21 homeless. These addicts brought to California by the substandard rehab industry, have further
22 contributed to the public's burden by discharging addicted homeless into the community who
23 require further care and rehabilitation at the public's expense, and who commit crimes in California
24 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
25 all relevant times when they deceptively marketed their products as non-addictive that such
26 addiction would be highly difficult to overcome. Defendants knew or should have known that
27 municipalities, including Santa Ana, would bear the burden of costs associated with rehabilitation
28 business of all types.

300. The role of Defendants’ deceptive marketing and distribution scheme in causing this public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.” And in August 2016, the former U.S. Surgeon General expressly connected the “urgent health crisis” to “heavy marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment specialists, and law enforcement and public health officials confirm that prescription opioids lawfully prescribed by doctors have fueled this epidemic.

301. Absent each Defendant’s deceptive marketing scheme and improper distribution, opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not only engaged in false advertising, they have also created or assisted in the creation of a public nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the present is part of its deceptive marketing and distribution scheme and subjects that Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

303. Accordingly, Defendants’ conduct, both individually and collectively, has violated and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Santa Ana does not seek to limit the ability of doctors in California to prescribe opioids. Santa Ana does not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, Santa Ana seeks an order requiring Defendants

1 to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations,
2 and to abate the public nuisance they have created. To redress and punish Defendants' previous and
3 current violations of law that cause and continue to cause harm to Santa Ana, Plaintiff seeks a
4 judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law.

5 304. By this action, Santa Ana further seeks to recoup tax dollars spent already for the
6 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
7 impact on this county and its communities, and to abate the opioid nuisance so Santa Ana will not
8 be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
9 wrongful conduct as alleged herein.

10 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
11 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
12 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
13 California spiked by 34% from 2011 to 2013.

14 306. Opioid abuse also contributes to a range of social problems including physical and
15 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
16 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
17 unemployment, and despair. More and more Santa Ana resources are needed to combat these
18 problems. The prescription opioid crisis also diminishes Santa Ana's available workforce,
19 decreases productivity, increases poverty, and requires greater governmental expenditures by Santa
20 Ana.

21 307. The prescription opioid crisis has directly financially injured Santa Ana. The crisis
22 has led to an increased demand for, *inter alia*, security services (such as police, EMS, detention),
23 child protective services, health services, clean-up services, and legal services. Santa Ana has also
24 had to hire additional staff and expend additional resources to manage the demand.

25 308. Santa Ana's medical services have seen an increase in opioid-related health
26 problems among Santa Ana residents, including, but not limited to, infants born with opioid-related
27 medical conditions. This has resulted in increased demand and increased expenses.

28 309. Santa Ana has also suffered substantial financial damages in the form of lost

1 productivity of Santa Ana employees and residents, lost economic activity, lost reputation and good
2 will, and the lost opportunity for growth. These damages have been suffered and continue to be
3 suffered directly by Santa Ana.

4 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
5 their homes and their families. Some will get treatment and fewer will successfully complete it;
6 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
7 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
8 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
9 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
10 drug transactions; or dying from opioid-induced heart or neurological disease.

11 311. Santa Ana also has suffered substantial financial damages in the form of lost taxes
12 paid by its residents and businesses as a result of lost earnings and productivity.

13 312. While the use of opioids has taken an enormous toll on Santa Ana and its residents,
14 Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in
15 revenue for drug companies like the Defendants. Indeed, on information and belief, each Defendant
16 experienced a material increase in sales, revenue, and profits from the unlawful conduct described
17 above.

18 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
19 **Asserting Statutes of Limitations As Defenses**

20 313. Defendants' conduct has continued from the early 1990s through today and remains
21 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
22 continuous injury. The damages have not occurred all at once but have continued to occur and have
23 increased as time progresses. The tort is not completed nor have all the damages been incurred until
24 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
25 public nuisance remains unabated.

26 314. Defendants are equitably estopped from relying upon a statute of limitations defense
27 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
28 assure the public that they were undertaking efforts to comply with their obligations under the

1 controlled substances laws, all with the goal of continuing to generate profits.

2 315. For example, a Cardinal Health executive claimed that it uses “advanced analytics”
3 to monitor its supply chain, and assured the public it was being “as effective and efficient as
4 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

5 316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
6 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
7 curbing the opioid epidemic in our country.”⁸⁷

8 317. Defendants, through their trade associations, filed an amicus brief that represented
9 that Defendants took their duties seriously, complied with their statutory and regulatory
10 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

11 318. Defendants purposely concealed their wrongful conduct, including by assuring the
12 public and governmental authorities that they were complying with their obligations and were
13 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
14 behavior by providing the public with false information about opioids and have continued to use
15 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
16 is continuing to this day.

17 319. Defendants have also concealed and prevented discovery of information, including
18 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
19 and illegal activities.

20 320. Defendants also lobbied Congress and actively attempted to halt DEA investigations
21

22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
24 [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[7b6c1998b7a0_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html) (last accessed December 21, 2017)

25 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
Opioid Abuse, Wash. Post, (Dec. 22, 2016), available at
26 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html)
[industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html) (last accessed December 21,
27 2017).

28 ⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

1 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
2 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a
3 distributor's license was raised.

4 321. In addition, the Defendants fraudulently attempted to convince the public that they
5 were complying with their legal obligations and working to curb the opioid epidemic.

6 322. Because the Defendants concealed the facts surrounding the opioid epidemic, Santa
7 Ana did not know if the existence or scope of the Defendants' misconduct, and could not have
8 acquired such knowledge earlier through the exercise of reasonable diligence.

9 323. Defendants intended that their false statements and omissions be relied upon,
10 including by Santa Ana, and its residents.

11 324. Defendants knew of their wrongful acts and had material information pertinent to
12 their discovery, but concealed that information from the public, including Santa Ana, and its
13 residents. Only Defendants knew of their widespread misinformation campaign and of their
14 repeated, intentional failures to prevent opioid diversion.

15 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
16 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
17 opioid crisis have only recently come to light.

18 326. Defendants had actual knowledge that their conduct was deceptive, and they
19 intended it to be deceptive.

20 327. Santa Ana was unable to obtain vital information regarding these claims absent any
21 fault or lack of diligence on Santa Ana's part.

22 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

23 **A. The Marketing Scheme**

24 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
25 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
26 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
27

28 ⁸⁹ See Higham and Bernstein, *supra* note 53.

1 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
2 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
3 long-term, chronic pain. Through their personal relationships, the members of this marketing
4 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
5 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
6 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

7 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
8 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
9 made misleading statements and misrepresentations about opioids that downplayed the risk of
10 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
11 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
12 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
13 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
14 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
15 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
16 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
17 formulations provide a solution to opioid abuse.

18 330. The marketing scheme devised, implemented and conducted by the Manufacturer
19 Defendants was designed to ensure that they unlawfully increased their sales and profits through
20 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
21 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
22 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
23 network as described above.

24 331. There was regular communication between the Manufacturer Defendants, Front
25 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
26 exchanged. Typically, the coordination, communication and payment occurred, and continues to
27 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
28 Defendants, Front Groups, and KOLs share information regarding overcoming objections and

1 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
2 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
3 each agreed and took actions to hide the scheme and continue its existence.

4 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'
5 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
6 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
7 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
8 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
9 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
10 their members and constituents. By failing to disclose this information, Front Groups perpetuated
11 the marketing scheme, and reaped substantial benefits.

12 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
13 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
14 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
15 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
16 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
17 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
18 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
19 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
20 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
21 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
22 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
23 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

24 334. As public scrutiny and media coverage focused on how opioids ravaged
25 communities in California and throughout the United States, the Front Groups and KOLS did not
26 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
27 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
28 using opioids for chronic pain.

1 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
2 categories of activities in furtherance of the marketing scheme. As described herein, the
3 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
4 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
5 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
6 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
7 and (d) efforts to limit prescriber accountability.

8 336. In addition to disseminating misrepresentations about the risks and benefits of
9 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
10 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
11 criticized or undermined the CDC Guidelines which represented "an important step – and perhaps
12 the first major step from the federal government - toward limiting opioid prescriptions for chronic
13 pain."

14 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
15 the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not
16 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
17 of the individuals who participated in the construction of these guidelines."

18 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
19 president, stating "that the CDC guideline makes disproportionately strong recommendations based
20 upon a narrowly selected portion of the available clinical evidence."

21 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
22 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
23 "neutral" and more "scientific" than the Manufacturer Defendants themselves. Without the work
24 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
25 scheme could not have achieved its common purpose.

26 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to
27 be prescribed and used for chronic pain throughout Santa Ana, and the epidemic continues to injure
28 Plaintiff, and consume the resources of Plaintiff's emergency health services and law enforcement

1 systems.

2 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
3 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
4 in the object of the scheme, and functioned within a structure designed to effectuate the scheme's
5 purpose.

6 **B. The Distribution Scheme**

7 342. Faced with the reality that they will now be held accountable for the consequences
8 of the opioid epidemic they created, members of the industry resort to "a categorical denial of any
9 criminal behavior or intent."⁹⁰ Defendants' actions went far beyond what could be considered
10 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
11 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
12 competitive, with the common purpose and achievement of vastly increasing their respective profits
13 and revenues by exponentially expanding a market that the law intended to restrict.

14 343. Knowing that dangerous drugs have a limited place in our society, and that their
15 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
16 and addiction causes to individuals, society and governments, California enacted California
17 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
18 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
19 to detect and report such activity.

20 344. If morality and the law did not suffice, competition dictates that the Distributor
21 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
22 if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior
23 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
24 dictates that it would do so.

25 345. The Distributor Defendants' scheme required the participation of all. If any one
26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

1 member broke rank, its compliance activities would highlight deficiencies of the others, and the
2 artificially high quotas they maintained through their scheme would crumble. But, if all the
3 members of the enterprise conducted themselves in the same manner, it would be difficult for state
4 authorities or the DEA to go after any one of them. Accordingly, through the connections they
5 made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the
6 Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly,
7 in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting
8 Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the
9 Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance
10 Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the
11 subsequent industry-wide enforcement actions and consent orders issued after that time, none of
12 them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult
13 to find the right balance between proactive anti-diversion efforts while not inadvertently limiting
14 access to appropriately prescribed and dispensed medications.” Yet, the Distributor Defendants
15 apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure
16 the largest possible financial return.

17 346. As described above, at all relevant times, the Distributor Defendants conspired
18 together for the purpose of unlawfully increasing sales, revenues and profits. In support of this
19 common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard
20 their statutory duties to identify, investigate, halt and report suspicious orders of opioids and
21 diversion of their drugs into the illicit market so that those orders would not result in a decrease, or
22 prevent an increase in, the necessary quotas.

23 347. At all relevant times, as described above, the Distributor Defendants exerted control
24 over, conducted and/or participated in distribution scheme by fraudulently claiming that they were
25 complying with their duties under California law to report suspicious orders and to maintain
26 systems to detect and report such activity.

27 348. While participating in their distribution scheme, Distributor Defendants applied
28 political pressure at the state and federal level to limit regulators’ ability to quickly and effectively

1 police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied
2 Congress to pass the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁹¹

3 349. The Distributor Defendants knowingly and intentionally furnished false or
4 fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material
5 information from reports, records and other document required to be filed with the California Board
6 of Pharmacy and the DEA including the Manufacturer Defendants’ applications for production
7 quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription
8 opioids and the diversion of their prescription opioids into the illicit market, and failed to report
9 this information to the California Board of Pharmacy and the DEA in their mandatory reports.

10 VI. MISCELLANEOUS FACTUAL ALLEGATIONS

11 350. FDA approval of opioids for certain uses did not give Defendants license to
12 misrepresent the risks and benefits of opioids. Indeed, Defendants’ misrepresentations were directly
13 contrary to pronouncements by and guidance from the FDA based on the medical evidence and
14 their own labels.

15 351. Defendants’ causal role in the opioid epidemic was not broken by the involvement
16 of doctors. Defendants’ marketing efforts were ubiquitous and highly persuasive. Their deceptive
17 messages tainted virtually every source doctors could rely on for information and prevented them
18 from making informed treatment decisions. Defendants also were able to harness and hijack what
19 doctors wanted to believe – namely, that opioids represented a means of relieving their patients’
20 suffering and of practicing medicine more compassionately.

21 ⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at
22 <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>
23 (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement*
24 *While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21,
25 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA*
26 *Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21,
27 2017); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston
28 *Gazette-Mail* (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 352. Each Defendant's conduct and role in creating or assisting in the creation of the
2 public health crisis now plaguing California is directly relevant to the amount of the civil penalties
3 to be awarded under California Business & Professions Code §.

4 353. As a members of the boards of various Purdue entities, the Sacklers oversaw all
5 aspects of Purdue's marketing and promotion of opioid products. As board members who were
6 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
7 known, of Purdue's deceptive marketing tactics of opioid products.

8 354. The Sackler Defendants also were aware of specific examples of deceptive
9 marketing through receipt of call note reviews in their capacities as board members. On information
10 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
11 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
12 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

13 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
14 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
15 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
16 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

17 356. By 2006, prosecutors at the United States Department of Justice found damning
18 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
19 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
20 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
21 events and side effects than other pain medications.

22 357. As members of the family that owns Purdue, the Sackler Defendants personally
23 benefitted from the success of OxyContin. At various points, as directors, they approved the
24 distribution of funds from Purdue to shareholders, including themselves and their extended family.

25 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
26 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
27 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
28 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of

Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy the opioid related liabilities of the companies from which they were transferred.

359. Plaintiff is informed and believes that due to the billions of dollars in profits that have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly profited and received the benefits of that wrongdoing.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)

360. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 359 above as if set forth fully herein.

361. California Civil Code § 3479 provides that “anything which is injurious to health ... or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property ... is a nuisance.”

362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

363. California Civil Code § 3490 states that “no lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right.”

364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought by Santa Ana to abate the public nuisance created by the Defendants.

365. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Santa Ana in violation of California Civil Code §§ 3479 and 3480.

1 366. The public nuisance is substantial and unreasonable. Defendants' actions caused and
2 continue to cause the public health epidemic described above in Santa Ana, and that harm
3 outweighs any offsetting benefit.

4 367. Defendants knew and should have known that their promotion and distribution of
5 opioids was false and misleading and that their deceptive marketing scheme would create or assist
6 in the creation of the public nuisance—i.e., the opioid epidemic.

7 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
8 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
9 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
10 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
11 so widespread, and the opioid epidemic that now exists would have been averted or much less
12 severe.

13 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
14 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
15 can be abated.

16 370. Each Defendant is liable for public nuisance because its conduct at issue is
17 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
18 endangers the safety, health, morals, comfort, or repose of a considerable number of people in Santa
19 Ana. Defendants' conduct is also indecent or offensive to the senses, and constitutes an obstruction
20 to the free use of property sufficient to constitute an interference with the people of Santa Ana's
21 comfortable enjoyment of life or property.

22 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
23 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
24 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
25 unreasonable interference with Santa Ana and its residents' public rights, including, but not limited
26 to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free
27 from disturbance and reasonable apprehension of danger to person or property.

28 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably

1 interfered with Santa Ana and its residents' public rights by, *inter alia*, engaging in a promotion
2 and marketing scheme that pushed the use of opioids for indications not federally approved, and by
3 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
4 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
5 Defendants failed to comply with federal law.

6 373. Defendants have also unlawfully and intentionally distributed opioids or caused
7 opioids to be distributed within and without Santa Ana absent effective controls against diversion.
8 Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain
9 effective controls against diversion include Defendants' failure to effectively monitor for
10 suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

11 374. Defendant's unreasonable interference with Santa Ana residents' public rights
12 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
13 expenditures to combat and address these harms. These damages have been suffered and continue
14 to be suffered directly by Santa Ana and its residents.

15 375. Defendants' actions have also created a palpable climate of fear, distress,
16 dysfunction and chaos among residents of Santa Ana where opioid diversion, abuse, and addiction
17 are prevalent and where diverted opioids are used frequently. Specifically, Defendants conduct has
18 caused, among other things, (a) routine separation of children from their parents who have fallen
19 victim to easy access to opioids and/or related crime; (b) children to have easy access and to become
20 addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for
21 loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces
22 and property; (e) property crimes throughout Santa Ana; (f) employers to lose the value of
23 productive and healthy employees; (g) increased public health and safety costs; (h) a reduction in
24 potential property values within Santa Ana; and (i) a decrease in tax revenues for Santa Ana.

25 376. The impact of Defendants' conduct on Santa Ana is of a continuing nature.
26 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

27 377. Defendants knew or should have known that their actions would lead to the national
28 opioid epidemic and to the resulting injuries to the public rights of Santa Ana.

1 378. Santa Ana has sustained a special and peculiar injury because its damages include,
2 *inter alia*, health service expenditures, public safety expenditures, payment of opioid addiction
3 treatment, decreased tax revenues, and a reduction in potential property values, and other costs
4 related to opioid addiction treatment and overdose prevention.

5 379. The externalized risks associated with Defendants' nuisance-creating conduct as
6 described herein greatly exceed the internalized benefits.

7 380. Defendants' actions are a direct and proximate contributing cause of the opioid
8 epidemic and the injuries to the public rights of Santa Ana and its residents.

9 381. Defendants, individually and collectively, are at the very least, a substantial factor
10 in causing the national opioid epidemic and of the injuries to Santa Ana and its residents.

11 382. The injuries to the public rights of Santa Ana and its residents are indivisible
12 injuries.

13 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
14 if unabated, will continue to cause an unreasonable interference with public rights of Santa Ana
15 and its residents.

16 384. Defendants' conduct is ongoing and persistent, and Santa Ana seeks all damages
17 flowing from Defendants' conduct. Santa Ana seeks economic losses (direct, incidental, and/or
18 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
19 above. Santa Ana does not seek damages for the wrongful death, physical personal injury, or
20 emotional distress caused by Defendants' actions.

21 385. Pursuant to Code of Civil Procedure § 731, Santa Ana requests an order providing
22 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
23 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

24 **SECOND CAUSE OF ACTION**
25 **(Fraud – Against All Defendants)**

26 386. Plaintiff realleges and incorporates herein by reference each and every allegation in
27 paragraphs 1 through 385 above as if set forth fully herein.

28 387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set

1 forth herein

2 388. The Defendants made fraudulent misrepresentations and omissions of material fact.
3 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
4 were intended to induce reliance.

5 389. Those misrepresentations and omissions were known to be untrue by the
6 Defendants, or were recklessly made.

7 390. As alleged herein, the Manufacturer Defendants engaged in false representations
8 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
9 dangers of abuse, and the risks of addiction.

10 391. As alleged herein, Defendants made false statements and/or omissions regarding
11 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
12 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
13 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
14 opioids, within Santa Ana.

15 392. Defendants made those misrepresentations and omissions in an intentional effort to
16 deceive Santa Ana and its residents, despite the Defendants' knowledge of the dangers of such use
17 of prescription opioids.

18 393. In addition and independently, Defendants had a duty not to deceive Plaintiff
19 because Defendants had in their possession unique material knowledge that was unknown, and not
20 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

21 394. The Defendants continued making those misrepresentations, and failed to correct
22 those material omissions, despite repeated regulatory settlements and publications demonstrating
23 the false and misleading nature of the Defendants' omissions and/or claims.

24 395. While Defendants had a duty to disclose the above-referenced material facts, they
25 nevertheless concealed them. These false representations and concealed facts were material to the
26 conduct and actions at issue. Defendants made these false representations and concealed facts with
27 knowledge of the falsity of their representations and did so with the intent of misleading Santa Ana,
28 its residents, the public, and persons on whom these entities relied.

1 396. Defendants intended and had reason to expect under the operative circumstances
2 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
3 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
4 and that these entities would act or fail to act in reasonable reliance thereon.

5 397. Santa Ana, its residents, and others, did in fact rightfully, reasonably, and justifiably
6 rely on Defendants' representations and/or concealments, both directly and indirectly.

7 398. For instance, doctors, including those serving Santa Ana and its residents, relied on
8 the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
9 Patients, including residents of Santa Ana, relied on the Defendants' misrepresentations and
10 omissions in taking prescription opioids for chronic pain relief.

11 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
12 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
13 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
14 effective response to the opioid crisis.

15 400. Defendants' misconduct alleged in this case is ongoing and persistent.

16 401. Santa Ana has experienced an unprecedented opioid addiction and overdose
17 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
18 services, and lost productivity to Santa Ana's workforce.

19 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
20 result of Defendants' fraudulent conduct.

21 403. As a direct and foreseeable consequence of Defendants' fraud, Santa Ana has
22 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
23 opioid addiction treatment and its secondary consequences in excess of those Santa Ana would
24 have otherwise incurred.

25 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
26 fraudulent, entitling Santa Ana to punitive damages.

27 ///

28 ///

THIRD CAUSE OF ACTION
(Negligence – Against All Defendants)

405. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 404 above as if set forth fully herein.

406. To establish actionable negligence in California, Plaintiff must show a duty, a breach of that duty, and injury resulting proximately therefrom.

407. Defendants have a duty to exercise reasonable care under the circumstances, in light of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

408. In addition, Defendants had a duty not to breach the standard of care established under California law, including 16 CCR § 1782 and California Business and Professions Code §§ 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject to abuse, and to develop and maintain systems to detect and report such activity.

409. Defendants voluntarily undertook a legal duty to prevent the diversion of prescription opioids by engaging in the distribution of prescription opioids and by making public promises to prevent the diversion of prescription opioids.

410. Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

411. Defendants knew of the highly addictive nature of prescription opioids and of the high likelihood of foreseeable harm to patients and communities, including Santa Ana, from prescription opioid diversion.

412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and in accordance with applicable standards of conduct in advertising, marketing, selling, and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and municipal government such as Santa Ana which must incur enormous expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the

1 need to address the consequences of a large number of residents that become addicted to opioids as
2 a result of Defendants' conduct.

3 413. As described throughout the Complaint, Defendants breached their duties to
4 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
5 monitor for, failing to report, and filling highly suspicious orders time and again.

6 414. As described throughout the Complaint, in language expressly incorporated herein,
7 Defendants misrepresented their compliance with their duties under the law and concealed their
8 noncompliance and shipments of suspicious orders of opioids to Santa Ana and destinations from
9 which they knew opioids were likely to be diverted into Santa Ana, in addition to other
10 misrepresentations alleged and incorporated herein.

11 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
12 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
13 purported benefits of long-term use of opioids for the treatment of chronic pain.

14 416. Manufacturer Defendants knew or should have known, that their affirmative
15 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
16 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
17 representatives, and internal documents, should have put them on notice that such harm was not
18 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
19 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
20 and the public.

21 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
22 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

23 418. Defendants' misconduct alleged in this case is ongoing and persistent.

24 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
25 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
26 great probability of causing substantial harm.

27 420. As is described throughout this Complaint, Defendants acted without even slight
28 diligence or scant care, and with indifference, and were negligent in a very high degree,

1 disregarding the rights and safety of other persons, and said actions have a great probability of
2 causing substantial harm.

3 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
4 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
5 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
6 minimize the risk of addiction in patients and resultant harm to those patients, their families and
7 their communities, and to taxpayers and municipal government such as Santa Ana, including, but
8 not limited to, the following:

- 9 a. Foreseeability of harm to Santa Ana: Defendants were aware or reasonably
10 should have been aware of the risk of addiction of a large number of patients in
11 places such as Santa Ana, and need for their care and treatment and in handling
12 other consequences of their addiction and that such costs would be borne by
13 local governments such as Santa Ana;
- 14 b. Degree of certainty Santa Ana suffered harm: Santa Ana has suffered enormous
15 harm and costs in addressing treatment of addicted patients, including but not
16 limited to expenditures for prevention, treatment, emergency response and law
17 enforcement costs and other foreseeable costs related to the need to address the
18 consequences of a large number of residents that become addicted to opioids as
19 a result of Defendants' conduct;
- 20 c. Closeness of connection between Santa Ana's harm: The explosion of opioid
21 addiction and the presence of opioid addicted patients in Santa Ana as a result
22 of Defendants' conduct has resulted in expenditures directly for prevention,
23 treatment, emergency response and law enforcement costs and other foreseeable
24 costs related to the need to address the consequences;

- 1 d. Moral blame attached to Defendants' conduct: Defendants' knew or should have
2 known that their wrongful conduct, actions and omissions would result in an
3 explosion of patients who would become addicted to opioids, and that a vast
4 opioid epidemic would result from the prescription of opioids to tens of millions
5 of patients nationwide, including within Santa Ana, and that the costs would be
6 borne by the state, county and municipal local governments, while Defendants
7 profited tens of billions of dollars collectively from the widespread use of
8 prescription opioid products;
- 9
10 e. Policy of preventing future harm: As a direct and foreseeable result of
11 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
12 to occur on a vast scale both nationally and locally in places such as Santa Ana
13 resulting in tremendous harm and cost to the patients, their families and the
14 communities in dealing with this epidemic and crisis, and there is a need to
15 ensure that the costs of such wrongful conduct is borne by Defendants so that
16 parties contemplating such or similar conduct in the future know they will be
17 held responsible for such harm;
- 18
19 f. Extent of burden to Defendants: There is no burden to Defendants in that state
20 and other law precludes them from engaging in the conduct alleged herein, and
21 there is no burden from precluding Defendants from profiting from their
22 wrongful conduct and operating within the confines of the law in advertising,
23 marketing, selling and distributing opioid products in a safe manner to minimize
24 the risk of addiction in patients and resultant harm to those patients, their
25 families and their communities, and to taxpayers and municipal government
26 such as Plaintiff Santa Ana; and
27
28

g. Consequences to the community of imposing a duty to exercise care with resulting liability for breach: Imposing a duty to not engage in Defendants' wrongful conduct of advertising, marketing, selling and distributing opioid products in an unsafe manner would minimize the risk of addiction in patients, and liability for a breach of this duty would benefit communities such as Santa Ana in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the country and the nation.

422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled substances laws cited above.

423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for security services, emergency, health, prosecution, corrections, and rehabilitation services, as well as the cost of opioid addiction treatment paid by Santa Ana.

424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

425. Defendants' breaches of their duty of care foreseeably and proximately caused damage to Santa Ana and its residents.

426. Manufacturer Defendants are guilty of negligence per se in that the Defendants violated applicable California laws, statutes, and regulations, in the manner in which they advertised, marketed, sold and distributed opioid products.

427. Distributor Defendants are guilty of negligence per se in that the Defendants violated California laws, statutes, and regulations designed to protect Plaintiff from the harms it has suffered, including, but not limited to, the following:

a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110390;

- b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that had been falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110395;
- c. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;
- d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;
- e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and
- f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Santa Ana. Santa Ana, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Santa Ana to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

430. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

431. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Santa Ana, including from opioids foreseeably and deliberately diverted within and into Santa Ana.

432. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

433. These expenditures include, but are not limited to, the provision of emergency medical services and treatment services to people who use opioids.

434. These expenditures have helped sustain Defendants' businesses.

435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices.

436. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and Plaintiff lacks a remedy provided by law.

438. Defendants' misconduct alleged in this case is ongoing and persistent.

439. Defendants have unjustly retained benefits to the detriment of Santa Ana, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

1 440. Santa Ana is entitled to restitution and disgorgement from Defendants in an amount
2 to be determined at trial.

3 **FIFTH CAUSE OF ACTION**
4 **(Civil Conspiracy – Against All Defendants)**

5 441. Plaintiff realleges and incorporates herein by reference each and every allegation in
6 paragraphs 1 through 440 above as if set forth fully herein.

7 442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
8 and/or distribution of opioids into California and Santa Ana.

9 443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
10 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
11 and Santa Ana.

12 444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
13 report, and prevent suspicious orders of opioids.

14 445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
15 conspiracy by increasing the volume of opioid sales in the United States through creating a market
16 for non-medical use of opioids of epidemic proportions.

17 446. Many of the Manufacturing Defendants are members, participants, and/or sponsors
18 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
19 the HDA to give further assistance to the conspiracy.

20 447. The Manufacturing Defendants hid from the general public and suppressed and/or
21 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
22 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
23 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

24 448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
25 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
26 to commit acts of fraud.

27 449. Indeed, for the Defendants’ fraudulent scheme to work, each of the Defendants had
28 to agree to implement similar tactics.

1 450. By intentionally refusing to report and halt suspicious orders of their prescription
2 opioids, Defendants engaged in a fraudulent scheme.

3 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
4 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
5 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
6 and were actually being diverted into the market of non-medical use.

7 452. Defendants further unlawfully marketed opioids in California and Santa Ana in
8 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
9 dissemination of false and misleading information about the safety and efficacy of long-term opioid
10 use through, among other things: (a) the use of “Front Groups” that appeared to be independent of
11 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
12 continuing medical education (“CME”) programs controlled and/or funded by the Defendants; (d)
13 hiring and deploying so-called “key opinion leaders” or “KOLs” who were paid by the Defendants
14 to promote their message; and (e) the “detailing” activities of the Defendants’ sales forces, which
15 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
16 physicians lacking the expertise of pain care specialists.

17 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
18 unbiased, independent patient-advocacy and professional organizations in order to disseminate
19 patient education materials, a body of biased and unsupported scientific “literature,” and “treatment
20 guidelines” that promoted the Defendants’ false messages.

21 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
22 influence prescribers’ habits by promoting the Defendants’ false message through, among other
23 things, writing favorable journal articles and delivering supportive CMEs as if they were
24 independent medical professionals, thereby further obscuring the Defendants’ role in the
25 conspiracy.

26 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
27 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
28 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of

activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work together with the Defendants to advance the conspiracy.

456. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes. Such allegations are specifically incorporated herein.

457. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and proximately caused the injuries alleged herein.

458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

459. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

461. Defendants' misconduct alleged in this case is ongoing and persistent.

462. As a result of Defendants' conspiracy, Santa Ana is entitled to compensatory damages in an amount to be proved at trial.

463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Santa Ana to punitive damages.

SIXTH CAUSE OF ACTION

(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)

464. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 463 above as if set forth fully herein.

1 465. California Business & Professions Code § 17500 makes it unlawful for a business
2 to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning
3 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
4 exercise of reasonable care should be known, to be untrue or misleading.”

5 466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
6 designed to disseminate false or misleading statements designed to promote the belief that opioid
7 drugs could safely be used in a non-addictive manner.

8 467. By way of example, Actavis’s predecessor created a patient brochure for Kadian in
9 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome
10 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

11 468. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back
12 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
13 claimed that it is “less likely if you have never had an addiction problem.”

14 469. Cephalon and Purdue sponsored research and publications that falsely and
15 deceptively stated opioids did not have “ceiling dose.”

16 470. Purdue created websites, available to the public that instructed patients to seek new
17 medical providers out if their current provider would not increase their dose.

18 471. Defendants’ false and deceptive advertising practices resulted in increased opioid
19 dosages being prescribed to Santa Ana’s residents, increasing the incidence of opioid addiction and
20 overdose in Santa Ana.

21 472. Distributor Defendants also repeatedly omitted material information and/or falsely
22 represented that they were effectively preventing diversion and were monitoring, reporting, and
23 preventing suspicious orders.

24 473. As alleged above, Defendants’ statements about the risks associated with opioid use
25 were not supported by or were contrary to the scientific evidence.

26 474. As alleged above, each Defendant’s conduct, separately and collectively, was likely
27 to deceive California payors who purchased or covered the purchase of opioids.

28 475. Santa Ana seeks restitution and injunctive relief under California Business &

1 Professions Code § 17535.

2 476. Santa Ana also seeks an order assessing a civil penalty of two thousand five hundred
3 dollars (\$2,500) against Defendants for each violation of California's False Advertising Law
4 pursuant to California Business & Professions Code § 17536.

5 **SEVENTH CAUSE OF ACTION**
6 **(Negligent Failure to Warn— Against Manufacturer Defendants)**

7 477. Plaintiff realleges and incorporates herein by reference each and every allegation in
8 paragraphs 1 through 476 above as if set forth fully herein.

9 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
10 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
11 adequately warning the medical profession about the risk of addiction from the use of opioid
12 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
13 cancel out, and render meaningless any written warnings given about the risk of addiction from the
14 use of opioid products.

15 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
16 to adequately warn the medical profession about the risk of addiction from the use of opioid
17 products, including by overpromoting and over-marketing opioid products in a manner so as to
18 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
19 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
20 products in situations and for patients who should not have been using those drugs or should have
21 used them only as a last resort before other means were used or other less addictive and dangerous
22 drugs were prescribed.

23 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
24 and overpromoting and over-marketing the use of prescription opioid products, there is now a
25 national opioid addiction epidemic, including in Santa Ana. The People of Santa Ana, as a further
26 direct and proximate consequence and result thereof, sustained injuries and damages including but
27 not limited to tax dollars spent and costs for treatment of opioid addicted patients, emergency
28 response costs, law and regulatory enforcement costs, opioid disposal programs, and measures for

1 prevention of further opioid abuse and addiction.

2 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
3 fraudulent, entitling Santa Ana to punitive damages.

4 **EIGHTH CAUSE OF ACTION**
5 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler**
6 **Defendants)**

7 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
8 paragraphs 1 through 481 above as if set forth fully herein.

9 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
10 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
11 possess a right to payment from Purdue.

12 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
13 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
14 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
15 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

16 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
17 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
18 including Plaintiff.

19 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
20 them pursuant to California Civil Code § 3439.04(a)(1).

21 **NINTH CAUSE OF ACTION**
22 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

23 487. Plaintiff realleges and incorporates herein by reference each and every allegation in
24 paragraphs 1 through 486 above as if set forth fully herein.

25 488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
26 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
27 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
28 of its judgment against Purdue entered in this action.

489. After the Sackler Defendants became aware in or about 1999 that Purdue faced

1 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
2 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping
3 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
4 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
5 Defendants and their extended family.

6 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
7 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
8 to commit acts of fraud.

9 491. Purdue and the Sackler Defendants acted with a common understanding or design
10 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
11 excuse, which directly and proximately caused the injuries alleged herein.

12 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
13 unlawfully, and without a reasonable or lawful excuse.

14 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
15 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
16 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
17 judgment entered in this action.

18 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
19 compensatory damages in an amount to be proved at trial.

20 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
21 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

22 **PRAYER FOR RELIEF**

23 WHEREFORE, Santa Ana and the People respectfully request judgment in their favor
24 granting the following relief:

- 25 a) Entering Judgment in favor of Santa Ana and the People in a final order against
26 each of the Defendants;
27
28

- b) An award of actual and consequential damages in an amount to be determined at trial;
- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff’s judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents

1 from selling, transferring, conveying, assigning, or otherwise disposing of any of
2 the property transferred to them by Purdue;

- 3 q) An order that the judgment granted herein be declared a lien against the property
4 transferred to the Sackler Defendants by Purdue;
- 5 r) An award of punitive damages;
- 6 s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- 7 t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to
8 California Code of Civil Procedure § 1021.5;
- 9 u) Pre- and post-judgment interest as allowed by law; and
- 10 v) Any other relief deemed just, proper, and/or equitable.

11 **PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE**

12 Dated: March 27, 2019

13 **ROBINS KAPLAN LLP**

14 By: 

15 Roman Silberfeld
16 Bernice Conn
17 Michael A. Geibelson
18 Lucas A. Messenger

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27
28
ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT E

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment
form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF SAN CLEMENTE;
(LO ESTÁ DEMANDANDO EL DEMANDANTE): and THE PEOPLE OF
THE STATE OF CALIFORNIA, by and through San Clemente
City Attorney Scott C. Smith

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. ¡AVISO! Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es):

San Francisco County Superior Court
Civic Center Courthouse
400 McAllister Street
San Francisco, CA 94102-4515

CASE NUMBER:
(Número del Caso):

CGC-19-574868

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783

310-552-0130 310-229-5800

Lucas A. Messenger, Bar No. 217645

ROBINS KAPLAN LLP

Los Angeles, CA 90067

DATE:

(Fecha) MAR 28 2019

CLERK OF THE COURT

Clerk, by

DE LA VEGA-NAVARRO, Rosaly Deputy
(Secretario) (Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

(SEAL)

NOTICE TO THE PERSON SERVED: You are served

- ☐ as an individual defendant.
- ☐ as the person sued under the fictitious name of (specify):

- ☐ on behalf of (specify):

under: ☐ CCP 416.10 (corporation)

☐ CCP 416.20 (defunct corporation)

☐ CCP 416.40 (association or partnership)

☐ other (specify):

☐ CCP 416.60 (minor)

☐ CCP 416.70 (conservatee)

☐ CCP 416.90 (authorized person)

- ☐ by personal delivery on (date):

COPIED
FAXED

SUM-200(A)

SHORT TITLE: City of San Clemente, et al. v. Purdue
Pharma L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

Page _____ of _____
 Page 1 of 1

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(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

CITY OF SAN CLEMENTE; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through San
Clemente City Attorney Scott C. Smith,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

Case No.

PLAINTIFFS' COMPLAINT FOR:

- 1. PUBLIC NUISANCE;**
- 2. FRAUD;**
- 3. NEGLIGENCE;**
- 4. UNJUST ENRICHMENT;**
- 5. CIVIL CONSPIRACY;**
- 6. FALSE ADVERTISING;**
- 7. NEGLIGENT FAILURE TO WARN;**
- 8. FRAUDULENT TRANSFER; and**

ENDORSED
FILED
Superior Court of California
County of San Francisco

MAR 28 2019

CLERK OF THE COURT
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Deputy Clerk

CGC - 19 - 574868

1 SACKLER, an individual; IRENE
 2 SACKLER LEFCOURT, an individual;
 3 BEVERLY SACKLER, an individual and
 4 as trustee for TRUST FOR THE BENEFIT
 5 OF MEMBERS OF THE RAYMOND
 6 SACKLER FAMILY; THERESA
 7 SACKLER, an individual; DAVID A.
 8 SACKLER, an individual; CEPHALON,
 9 INC.; TEVA PHARMACEUTICAL
 10 INDUSTRIES, LTD.; TEVA
 11 PHARMACEUTICALS USA, INC.;
 12 JANSSEN PHARMACEUTICALS, INC.;
 13 JOHNSON & JOHNSON; ORTHO-
 14 MCNEIL-JANSSEN
 15 PHARMACEUTICALS, INC.; JANSSEN
 16 PHARMACEUTICA, INC.; ENDO
 17 HEALTH SOLUTIONS INC.; ENDO
 18 PHARMACEUTICALS INC.; ACTAVIS
 19 PLC; WATSON PHARMACEUTICALS,
 20 INC.; WATSON LABORATORIES, INC.;
 21 ACTAVIS PHARMA, INC.; ACTAVIS
 22 LLC; ALLERGAN PLC; ALLERGAN,
 23 INC.; ALLERGAN USA, INC.; INSYS
 24 THERAPEUTICS, INC.;
 25 MALLINCKRODT, PLC;
 26 MALLINCKRODT, LLC; CARDINAL
 27 HEALTH, INC.;
 28 AMERISOURCEBERGEN
 CORPORATION; MCKESSON
 CORPORATION; and
 DOES 1-100, inclusive,

Defendants.

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to San Clemente Through Illicit Channels	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to San Clemente Through Illicit Channels.....	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on San Clemente	72
I.	The Statutes of Limitations Are Tolerated and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

1 public safety connected to the opioid epidemic within San Clemente, including police, emergency
 2 response services, and detention centers; (f) increased burden on San Clemente's code enforcement
 3 programs; (g) re-education of doctors and patients about the appropriate use of opioids; and (h)
 4 extensive clean-up of public parks, spaces, and facilities. At the same time, San Clemente has seen
 5 a reduction to tax revenues caused by the epidemic created by the Defendants. Almost every citizen
 6 of San Clemente has been affected. The resulting damage to San Clemente was directly and
 7 foreseeably caused by Defendants' actions.

8 7. These increased costs could have been—and should have been—prevented by the
 9 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
 10 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
 11 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
 12 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
 13 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
 14 protecting opioids from theft, misuse, and diversion.

15 8. Instead of acting with reasonable care and in compliance with their legal duties,
 16 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
 17 process.

18 9. At the same time, Defendants flooded the market with false statements designed to
 19 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
 20 claims were false.³

21 10. Defendants' actions have not only caused significant costs, but have also created a
 22 palpable climate of fear, distress, dysfunction and chaos among San Clemente residents where
 23 opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used
 24 frequently.

25 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
 26 and/or unlawful conduct.

27
 28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. San Clemente, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. San Clemente has standing to recover damage incurred because of Defendants' actions and omissions. San Clemente has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical’s products and Janssen’s profits inure to J&J’s benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as “Actavis”).

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

1 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
2 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
3 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
4 California with the California Secretary of State.

5 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
6 principal place of business located in Chandler, Arizona.

7 38. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source
8 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
9 United States, including California. Subsys was indicated by the FDA for the treatment of
10 breakthrough cancer pain that other opioids could not eliminate.

11 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
12 bribe physicians with purported speaking fees for marketing and education events in exchange for
13 them prescribing Subsys for off-label uses. Insys’ founder and several other former Insys executives
14 were recently indicted by federal prosecutors on racketeering charges, alleging that these
15 individuals approved and fostered fraudulent behavior against insurance companies and also
16 conspired to bribe practitioners in various states. Insys Group is registered to do business in
17 California with the California Secretary of State.

18 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
19 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
20 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
21 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
22 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

23 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
24 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
25 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
26 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
27 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
28 Products are registered to do business in California with the California Secretary of State.

42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Allergan, Actavis, Insys, and Mallinckrodt are the “Manufacturer Defendants.”

C. The Distributor Defendants

43. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

44. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with San Clemente and its residents, and has purposefully availed itself of the advantages of conducting business with and within San Clemente. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

45. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

46. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with San Clemente and its residents, and has purposefully availed itself of the advantages of conducting business with and within San Clemente. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

48. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with San Clemente and its residents, and has purposefully availed itself of the advantages of conducting business with and within San Clemente. McKesson is in the chain of distribution of prescription opioids. McKesson

1 Corporation is registered to do business in California with the California Secretary of State.

2 49. The data which reveals and/or confirms the identity of the other wrongful opioid
3 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
4 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
5 voluntarily disclose the data necessary to identify with specificity the transactions which will form
6 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

7 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
8 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
9 listed on the New York Stock Exchange and their principal business consists of the nationwide
10 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
11 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
12 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
13 suspicious orders. San Clemente has reason to believe each has engaged in unlawful conduct which
14 resulted in the distribution, dispensing, and diversion of prescription opioids into San Clemente.
15 San Clemente names each of the "Big 3" herein as defendants and places the industry on notice that
16 San Clemente is acting to abate the public nuisance plaguing its community. Distributor Defendants
17 have had substantial contacts and business relationships with the People. Distributor Defendants
18 have purposefully availed themselves of business opportunities within San Clemente.

19 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
20 Defendants."

21 **D. The Doe Defendants**

22 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
23 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
24 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
25 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
26 is informed and believes, and on such information and belief alleges, that each of the Defendants
27 named as a DOE is responsible in some manner for the events and occurrences alleged in this
28 Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

53. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising and unlawful, unfair, and deceptive business practices, negligent acts, and creating or assisting in the creation of a public nuisance in San Clemente, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

54. Venue is proper in this Court because Defendants transact business in California and San Francisco County, and some of the acts complained of occurred in this venue. Furthermore, Defendant Distributor McKesson's principal place of business is in San Francisco County, and McKesson conducted business and continues to do business throughout the United States and in the State of California by regularly and continuously distributing prescription opioids throughout the State of California.

IV. GENERAL FACTUAL ALLEGATIONS**A. An Overview of the Opioid Epidemic**

55. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death."⁵

56. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

57. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

1 director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have
2 very, very high inherent risks . . . and there's no such thing as a fully safe opioid."⁶

3 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
4 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
5 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

6 59. Before the 1990s, generally accepted standards of medical practice dictated that
7 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
8 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
9 patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as
10 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
11 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
12 generally did not prescribe opioids for chronic pain.

13 60. The market for chronic pain patients, however, was much larger, and to take
14 advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for
15 chronic pain.⁷

16 61. As described herein, Defendants engaged in conduct that directly caused doctors to
17 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
18 obligations to prevent diversion of the highly addictive substance.

19 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
20 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
21 for every person in the United States to have a bottle of pills. This represents an increase of 300%
22 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
23 were dispensed per 100 persons.

24 63. Many Americans, including Californians and residents of San Clemente, are now
25

26 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

27 ⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times
28 (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United
 2 States, an increase of more than 22 percent over the previous year. The New York Times reported
 3 in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly
 4 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 5 a public health emergency by the President of the United States. The wave of opioid addiction was
 6 created by the increase in prescriptions.

7 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 8 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 9 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 10 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 11 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 12 80 percent of people who use heroin first misused prescription opioids.

13 65. Drug overdose deaths among all Americans increased more than 200 percent
 14 between 1999 and 2015.

15 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 16 there were 4,654 total opioid overdose deaths in 2016.⁹

17 ///

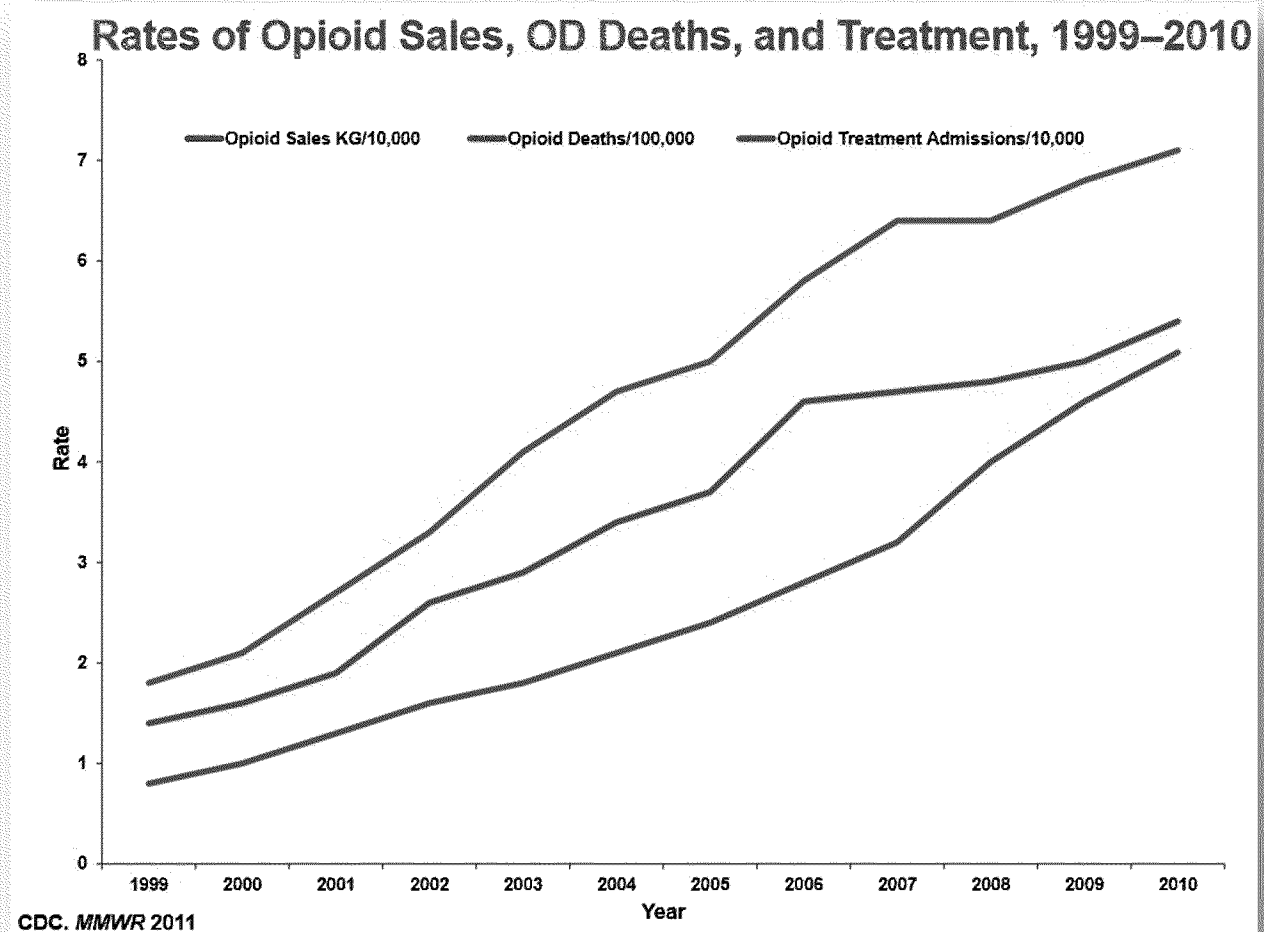
18 ///

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26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*,” N.Y.
 27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, *California Opioid Summary*, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in San Clemente, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants’ messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
2 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
3 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
4 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
5 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
6 carried a low, or no, risk of addiction.

7 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
8 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
9 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
10 of actual addiction began appearing, and advocated that the signs of addiction should be treated
11 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
12 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
13 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
14 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
15 opioid use, including the supposed ability of opioids to improve function and quality of life, even
16 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
17 claims.

18 75. These statements were not only unsupported by or contrary to the scientific
19 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
20 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
21 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

22 76. The Manufacturer Defendants began their marketing schemes decades ago and
23 continue them today.

24 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
25 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
26 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
27
28

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
 24

25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 29, 2017).

27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 100. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
6 unbranded advertising stated that “People who take opioids as prescribed usually do not become
7 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use.”

10 101. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 104. For example, the New York Attorney General (“NY AG”) found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in San Clemente and doctors treating residents of San Clemente.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 _____
28 ²³ Dr. Portenoy was a member of the board of the APF.

²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 119. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 120. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 121. On information and belief, AAPM is viewed internally by Endo as “industry

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26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 122. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

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27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in San Clemente during the relevant time period, are still available online, and were
 12 often reprinted in the Journal of Pain, which is the official journal of the American Pain Society.
 13 The Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 126. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 128. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 129. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 130. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 131. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
marketing materials along with the rights to Kadian, it appears that Actavis
continued to use this brochure in 2009 and beyond.
- 25 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
26 People Living with Pain (2007), which suggests that addiction is rare and
27 limited to extreme cases of unauthorized dose escalations, obtaining
28 duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in San Clemente, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 138. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain *is under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in San Clemente, to PartnersAgainstPain.com, which contained false
14 and misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 **Deceptive Claims of Pseudoaddiction**

22 139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
some of its proponents” and reported that despite the fact that Endo trained its sales representative
to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
Management testified to [the NY AG] that he was not aware of any research validating the
‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 141. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including San Clemente
the reliability and effectiveness of screening or monitoring patients as a tool
for managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

1 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
 2 widely believed by doctors to detect and deter abuse—“for improving outcomes related to
 3 overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that
 4 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
 5 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
 6 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

7 143. To underplay the risk and impact of addiction and make doctors feel more
 8 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
 9 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
 10 failed to disclose the increased difficulty of stopping opioids after long-term use.

11 144. For example, on information and belief, a 2011 non-credit educational program
 12 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
 13 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

14 145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
 15 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
 16 by gradually decreasing the dose of medication during discontinuation” without mentioning any
 17 hardships that might occur.³⁸ This publication was available on APF’s website until the
 18 organization dissolved in May 2012.

19 146. Detailers for Janssen have told and continue to tell doctors in California, including
 20 San Clemente, that their patients would not experience withdrawal if they stopped using opioids.

21 **Deceptive Minimization of Opioid Withdrawal**

22 147. The Manufacturer Defendants also deceptively minimized the significant symptoms
 23 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
 24 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
 25 understated the difficulty of tapering, particularly after long-term opioid use.

26 148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

27
 28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that “more than a few days of exposure to opioids significantly increases hazards” and “each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk

149. The Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants, are described below:

- a. On information and belief, Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’ acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in San Clemente that they should increase the dose of OxyContin,
rather than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was **no** evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in San Clemente, that Opana ER is harder to abuse and given demonstrations to
22 nurse practitioners about Opana ER’s purported abuse deterrent properties.

23
24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
[push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
[ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

1 157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements
2 in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those
3 statements to be false and misleading because there was no difference in the ability to extract the
4 narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge
5 of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy
6 benefit managers.

7 158. Because Orpana ER could be “readily prepared for injection” and was linked to
8 outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that
9 Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on
10 June 8, 2017, and requested that Endo withdraw Opana ER from the market.

11 159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of
12 its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not
13 market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and
14 believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-
15 called abuse deterrent properties of Purdue’s opioid products as a primary selling point to
16 differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim
17 that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim
18 that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to
19 yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids
20 are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral
21 abuse or misuse, and that its abuse deterrent properties can be defeated.

22 160. These statements and omissions by Purdue are false and misleading, and conflict
23 with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates
24 that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent
25 properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent
26 properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD
27 opioids prevent or reduce abuse, misuse, or diversion.

28 161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 27 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 28 430.

⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose
 epidemic*, Business Insider (Mar. 14, 2016), available at [http://www.businessinsider.com/robert-califf-
 abuse-deterrent-drugs-have-a-big-flaw-2016-3](http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3) (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in San Clemente, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewharper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

174. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

26 _____
27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs
despite knowing about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful,
26 unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their own role
27 in the deceptive marketing of chronic opioid therapy by funding and working through third parties
28 like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed

1 credibility of these individuals and organizations, and relied on them to vouch for the accuracy and
2 integrity of the Manufacturer Defendants' false and misleading statements about the risks and
3 benefits of long-term opioid use for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by San Clemente.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

26 _____
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
28 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

⁵² *Id.*

1 misrepresentations deceived and continue to deceive doctors and patients in California, including
2 in San Clemente, about the risks and benefits of long-term opioid use. California doctors confirm
3 this. Studies also reveal that many doctors and patients are not aware of or do not understand these
4 risks and benefits. Indeed, patients often report that they were not warned they might become
5 addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than
6 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.
7 Plaintiff is informed and believes that California residents were never told that they might become
8 addicted to opioids when they started taking them, were told that they could easily stop using
9 opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

10 192. Numerous doctors and substance abuse counselors in California note that many of
11 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
12 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
13 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
14 for opioid addiction.

15 193. The Manufacturer Defendants knew and should have known that their
16 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
17 when they made them.

18 194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
19 properties of their opioids and unlawful and unfair business practices caused and continue to cause
20 doctors in California, including doctors in San Clemente, to prescribe opioids for chronic pain
21 conditions such as back pain, headaches, arthritis, and fibromyalgia, rather than prescribing less
22 addictive medications. Absent Manufacturers Defendants' deceptive marketing scheme and their
23 unlawful and unfair business practices, these doctors would not have prescribed as many opioids
24 to as many patients, and there would not have been as many opioids available for misuse and abuse
25 or as much demand for those opioids.

26 195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
27 their opioids and their unlawful and unfair business practices have caused and continue to cause
28 the prescribing and use of opioids to explode in California, including in San Clemente. Opioids are

1 the most common means of treatment for chronic pain; 20% of office visits now include the
2 prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid.

3 196. In California, including San Clemente, Manufacturer Defendants' deceptive
4 marketing of the abuse-deterrent properties of their opioids during the past few years has been
5 particularly effective. For example, one survey reports that pain specialists were more likely to
6 recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically
7 because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent
8 properties were using more of it than those who did not know it was an AD opioid. Although sales
9 of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold
10 in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or
11 approximately 25% in opioid sales revenue in 2015).

12 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
13 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
14 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
15 that spending had tripled to \$288 million.

16 **E. All Defendants Created an Illicit Market for Opioids**

17 198. In addition to the allegations above, all Defendants played a role in the creation of
18 an illicit market for prescription opioids, further fueling the opioid epidemic.

19 199. Defendants' distribution of opioids was driven by national policies, coordination,
20 plans, and procedures that were the same in California as they were across the rest of the United
21 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
22 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
23 vastly increasing their respective profits and revenues by exponentially expanding a market that the
24 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
25 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
26 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
27 possible financial return.

28 200. Each participant in the supply chain shares the responsibility for controlling the

1 availability of prescription opioids. Opioid “diversion” occurs whenever the supply chain of
2 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
3 distribution or use to an illegitimate channel of distribution or use.

4 201. Diversion can occur at any point in the opioid supply chain.

5 202. For example, diversion can occur at the wholesale level of distribution when
6 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
7 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
8 size, orders that are disproportionately large in comparison to the population of a community served
9 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

10 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
11 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
12 usual course of practice. Some of the signs that a prescription may have been issued for an
13 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
14 different doctors (known as doctor shopping), when they travel great distances between the doctor
15 or their residence and the pharmacy to get the prescription filled, when they present multiple
16 prescriptions for the largest dose of more than one controlled substance, or when there are other
17 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
18 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
19 to treat a legitimate medical condition.

20 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
21 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
22 Opioids can also be diverted when stolen by employees or others.

23 205. Opioid diversion occurs at an alarming rate in the United States.

24 206. Each participant in the supply chain, including each Defendant, has a common law
25 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
26 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
27 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
28 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the best position to protect Plaintiff and the public from the risk of harm of misuse of these products. Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that duty in their misleading and inaccurate promotion of prescription opioids.

209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in their failure to prevent diversion of prescription opioids and in their refusal to report and halt suspicious orders.

210. In addition to their common law duties, Defendants possess duties under California law to develop and maintain a system to track suspicious orders of prescription opioids. Both Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR § 1782, and Distributor Defendants are further subject to California Business & Professions Code §§ 4164 and 4169.1.

211. Separately, Defendants also are subject to federal statutory requirements of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572.

212. Defendants' repeated and prolific violations of these requirements show that they have failed to meet the relevant standard of conduct that society expects of them: the duty to exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with willful disregard for San Clemente and the people therein.

213. California law requires Defendants to report suspicious orders of dangerous drugs subject to abuse, and to develop and maintain systems to detect and report such activity. This framework acts as a system of checks and balances from the manufacturing level through delivery

1 of the controlled substance to the patient or ultimate user.

2 214. Thus, all opioid distributors are required to maintain effective controls against
3 opioid diversion. They are required to create and use a system to identify and report to the California
4 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
5 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
6 and/or orders of unusual frequency. To comply with these requirements, distributors must know
7 their customers, must conduct due diligence, must report suspicious orders, and must terminate
8 orders if there are indications of diversion.

9 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
10 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
11 their obligations under the CSA.

12 216. Under the CSA, anyone authorized to handle controlled substances must track
13 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
14 automated drug reporting system that records and monitors the flow of Schedule II controlled
15 substances from the point of manufacture through distribution to the point of sale. ARCOS
16 accumulates data on distributors' controlled substances and transactions, which are then used to
17 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
18 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
19 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
20 and current record of each substance manufactured, imported, received, sold, delivered, exported,
21 or otherwise disposed of.

22 217. Plaintiff does not bring causes of action based on violations of federal statutes and
23 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
24 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
25 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
26 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
27 prescription opioids.
28

1. The Distributor Defendants Negligently Failed to Control the Flow of Opioids to San Clemente Through Illicit Channels

218. The Distributor Defendants have been and continue to be well-aware of problems posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes that the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. The distributors are also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor Defendants should look for in order to identify potential diversion.

219. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

220. Since 2008, the DEA also has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 San Clemente and its residents. Each Distributor Defendant knew or should have known that the
7 opioids reaching San Clemente were not being consumed for medical purposes and that the amount
8 of opioids flowing to San Clemente was far in excess of what could be consumed for medically
9 necessary purposes.

10 232. The Distributor Defendants negligently or intentionally failed to adequately control
11 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
12 substances would have anticipated the danger of opioid diversion and protected against it by, for
13 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
14 greater oversight, security, and control of supply channels; (c) looking more closely at the
15 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
16 amounts greater than the populations in those areas would warrant; (d) investigating demographic
17 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
18 San Clemente; (e) providing information to pharmacies and retailers about opioid diversion; and
19 (f) in general, simply following applicable statutes, regulations, professional standards, and
20 guidance from government agencies and using a little bit of common sense.

21 233. On information and belief, the Distributor Defendants made little to no effort to visit
22 the pharmacies servicing the areas around San Clemente to perform due diligence inspections to
23 ensure that the controlled substances the Distributor Defendants had furnished were not being
24 diverted to illegal uses.

25 234. On information and belief, the compensation the Distributor Defendants provided
26 to certain of their employees was affected, in part, by the volume of their sales of opioids to
27 pharmacies and other facilities servicing the areas around San Clemente, thus improperly creating
28 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid

1 abuse.

2 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
3 flooding the market in and around San Clemente with highly addictive opioids would allow opioids
4 to fall into the hands of children, addicts, criminals, and other unintended users.

5 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
6 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
7 and death. It was also reasonably foreseeable that many of these injuries would be suffered by San
8 Clemente residents, and that the costs of these injuries would be borne by San Clemente.

9 237. The Distributor Defendants knew or should have known that the opioids being
10 diverted from their supply chains would contribute to the opioid epidemic faced by San Clemente,
11 and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
12 addiction, demand, illegal transactions, economic ruin, and human tragedy.

13 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
14 and around San Clemente, but, on information and belief, they nevertheless persisted in a pattern
15 of distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
16 with such frequency that they knew or should have known these commonly abused controlled
17 substances were not being prescribed and consumed for legitimate medical purposes.

18 239. The use of opioids by San Clemente residents who were addicted or who did not
19 have a medically necessary purpose could not have occurred without the knowing cooperation,
20 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
21 Defendants adhered to effective controls to guard against diversion, San Clemente and its residents
22 would have avoided significant injury.

23 240. The Distributor Defendants made substantial profits over the years based on the
24 diversion of opioids into San Clemente. The Distributor Defendants knew that San Clemente would
25 be unjustly forced to bear the costs of these injuries and damages.

26 241. The Distributor Defendants' intentional distribution of excessive amounts of
27 prescription opioids showed an intentional or reckless disregard for the safety of San Clemente and
28 its residents. Their conduct poses a continuing threat to the health, safety, and welfare of San

1 Clemente.

2 242. The state laws at issue here are public safety laws.

3 243. The Distributor Defendants' violations constitute prima facie evidence of
4 negligence under state law.

5 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
6 **of Opioids to San Clemente Through Illicit Channels**

7 244. The same legal duties to prevent diversion, and to monitor, report, and prevent
8 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
9 were also legally required of the Manufacturer Defendants under California law.

10 245. In addition to a common law duty to exercise reasonable care in the promotion and
11 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
12 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
13 determined by the Board. *See* 16 CCR 1782.

14 246. On information and belief, for over a decade the Manufacturer Defendants have
15 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
16 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
17 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
18 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
19 Manufacturer Defendants breached their duties under state law.

20 247. The Manufacturer Defendants had access to and possession of the information
21 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
22 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
23 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
24 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
25 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
26 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
27 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
28 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer

1 Defendants built receipt of this information into the payment structure for the opioids provided to
2 the opioid distributors.

3 248. The Manufacturer Defendants' actions and omission in failing to effectively prevent
4 diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful
5 diversion of opioids into San Clemente.

6 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

7 249. As the demand for prescription opioids grew, fueled by their potency and purity,
8 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
9 traveling across state, city, and county lines in a variety of ways.

10 250. First, prescriptions written in one state would, under some circumstances, be filled
11 in a different state. But even more significantly, individuals transported opioids from one
12 jurisdiction specifically to sell them in another.

13 251. When authorities in one state cracked down on opioid suppliers, out-of-state
14 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
15 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
16 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
17 practice became so common that authorities dubbed these individuals "prescription tourists."

18 252. The facts surrounding numerous criminal prosecutions illustrate this common
19 practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught
20 flying to California in attempts to obtain additional sources of supply for their drug operation which
21 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

22 253. In another example, a man from Warren County, Ohio, who was sentenced to four
23 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
24 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
25 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a

26 _____
27 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

28 ⁵⁹ Andrew Welsh-Huggins, Associated Press, '*Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-

1 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
2 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
3 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
4 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
5 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
6 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

7 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
8 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
9 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
10 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
11 customers were from other states.⁶³

12 255. In yet another case, defendants who operated a pill mill in south Florida within
13 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
14 transported oxycodone back to the area for both use and distribution by local drug trafficking
15 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
16 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
17 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
18 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
19 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
20

21 [painkillers/#.WtdyKE2Wy71](#) (last updated July 8, 2012, 12:28 PM).

22 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
<http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
23 accessed July 25, 2018).

24 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
25 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

26 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
27 accessed July 25, 2018).

28 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
[patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

1 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
2 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
3 Kentucky residents.”⁶⁵

4 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
5 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
6 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
7 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
8 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
9 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
10 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
11 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
12 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

13 257. While the I-75 corridor was well utilized, prescription tourists also came from other
14 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
15 mills come from as far away as Arizona and Nebraska.⁷⁰

16 258. Similar pipelines developed in other regions of the country. For example, the I-95
17 corridor was another transport route for prescription pills. As the director of the Maine Drug
18 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
19 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
20

21 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s*
24 *Deadliest Drug Epidemic* 171 (2016).

25 ⁶⁷ *Id.* at 172

26 ⁶⁸ *Id.* at 171

27 ⁶⁹ *Id.*

28 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
(last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
(last accessed July 25, 2018)

1 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
2 Ohio, and Kentucky.

3 259. Along the west coast, over a million pills were transported from the Lake Medical
4 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²
5 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
6 Everett-based dealer who received the pills from southern California wore a diamond necklace in
7 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
8 OxyContin—connecting Los Angeles and Washington state.

9 260. Defendants certainly were aware, or should have been aware, that pill mills from
10 around the country were pushing its products. Defendants purchased nationwide, regional, state,
11 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
12 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
13 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
14 compute, and track their competitors' sales, and to compare and analyze market share information.

15 261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
16 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
17 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
18 regarding competing drugs, and analyzed the market share of those drugs.

19 262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
20 rewarded sales representatives who happened to have pill mills within their territories, enticing
21 those representatives to look the other way even when their in-person visits to such clinics should
22 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
23 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
24 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
25 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric

26
27 ⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and
Heartbreak, Los Angeles Times (July 10, 2016), available at [http://www.latimes.com/projects/la-me-
oxycontin-everett/](http://www.latimes.com/projects/la-me-
oxycontin-everett/) (last accessed July 25, 2018)

28 ⁷³ *Id.*

1 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
2 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
3 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
4 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
5 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

6 ⁷⁴

7 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
8 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
9 sales representative "it was packed with a line out the door, with people who looked like gang
10 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
11 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
12 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
13 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
14 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
15 2010 to inform the authorities.

16 264. Abundant evidence, thus, establishes that prescription opioids migrated between
17 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
18 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
19 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
20 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
21 prescription opioid pills were hard to get in one area, they migrated from another. The
22 manufacturers and distributors were fully aware of this phenomenon and profited from it.

23 265. Defendants each knew or should have known that opioid diversion and abuse was
24 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide

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26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

1 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
2 allowed to continue the unlawful diversion of opioids into San Clemente.

3 **G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the**
4 **Harm Alleged Herein and Substantial Damages**

5 266. As the Manufacturer Defendants' efforts to expand the market for opioids increased,
6 so have the rates of prescription and the sale of their products, as well as the rates of opioid-related
7 substance abuse, hospitalization, and death among San Clemente residents and across the nation.
8 Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of
9 opioids into communities like San Clemente, fueling the epidemic.

10 267. There is a "parallel relationship between the availability of prescription opioid
11 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
12 associated adverse outcomes."⁷⁷

13 268. Opioids are widely diverted and improperly used, and the widespread use of the
14 drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

15 269. The epidemic is "directly related to the increasingly widespread misuse of powerful
16 opioid pain medications."⁷⁹

17 270. The increased abuse of prescription opioids—along with growing sales—has
18 contributed to a large number of overdoses and deaths.

19 271. As shown above, the opioid epidemic has escalated in San Clemente with
20 devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror
21 Defendants' increased distribution of opioids.

22 272. Because of the well-established relationship between the use of prescription opioids
23 and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to San
24 Clemente and areas from which opioids are being diverted to San Clemente, has caused the opioid
25 epidemic to include heroin addiction, abuse, and death.

26 _____
27 ⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N.
Eng. J. Med. 241 (2015).

28 ⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in San Clemente.

274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in San Clemente.

275. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in San Clemente.

276. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in San Clemente. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by San Clemente and residents of San Clemente.

277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which San Clemente seeks relief, as alleged herein. San Clemente also seeks the means to abate the epidemic created by the Defendants.

278. San Clemente seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

279. San Clemente seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

280. San Clemente seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

281. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

282. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at <https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and->

283. The community-based problems require community-based solutions that have been limited by budgetary constraints.

284. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opioids, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon San Clemente.

285. The opioid epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

286. The Defendants have abandoned their duties imposed by the law, taken advantage of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in San Clemente.

287. In the course of conduct described in this Complaint, Defendants have acted with oppression, fraud, and malice, both actual and presumed.

H. The Impact of Opioid Abuse on San Clemente

288. Defendants' creation, through false and misleading advertising and a failure to prevent diversion, of a virtually limitless opioid market has significantly harmed San Clemente and resulted in an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be associated with the consumption of a counterfeit version of the prescription drug Norco (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has

[effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf](#) (last accessed January 8, 2018).

1 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
 2 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
 3 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further
 4 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
 5 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
 6 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
 7 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
 8 related overdoses, with 55% of those resulting from prescription opioids.

9 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
 10 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
 11 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
 12 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
 13 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

14 291. Even San Clemente's youngest residents bear the consequences of the opioid abuse
 15 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
 16 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
 17 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
 18 Many San Clemente women have become addicted to prescription opioids and have used these
 19 drugs during their pregnancies. As a result, many San Clemente infants suffer from opioid
 20 withdrawal and Neonatal Abstinence Syndrome ("NAS").⁸⁵

21 _____
 22 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
 23 *year*, LA Times (Oct. 27, 2014), available at [http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html)
 24 [prescription-hospital-er-20141026-story.html](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html) (last accessed December 21, 2017).

25 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
 26 *The Opioid Crisis in Indian Country*, at 37, available at
 27 <https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
 28 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US, 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
 Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
 21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at

292. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation can cost thousands of dollars for each occurrence.

293. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

294. Many of the parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

295. Opioid addiction is now the primary reason that Californians seek substance abuse treatment, and admissions to drug treatment facilities in California more than doubled from 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one facility in northern California, up to 90% – started on legal opioid prescriptions.

296. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in California. California faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]” and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting worse.

297. There is little doubt that each Defendant's deceptive marketing and distribution scheme has precipitated this public health crisis in California, including San Clemente, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids

<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 has created a population of patients physically and psychologically dependent on them (the
2 demand). And when those patients can no longer afford or legitimately obtain opioids, they often
3 turn to the street to buy prescription opioids or even heroin.

4 298. The effects of Defendants' deceptive marketing and distribution scheme has further
5 impacted Plaintiff in a foreseeable way such that San Clemente must devote increased resources to
6 the burden of the addicted homeless who commit drug and property crimes, to feed their addiction.
7 For example, tax dollars are required to maintain public safety of places where the addicted
8 homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required
9 to fight the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
10 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
11 *aureus* (MRSA) are spread by opioid abuse.

12 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
13 have recruited addicts nationally with false and misleading promises of the medically supervised
14 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
15 effective rehabilitation available in beautiful California communities. These for-profit
16 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
17 that many have provided substandard care including use of physicians who have had their license
18 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
19 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
20 as long as there are third party payments available, and then throw them out of the facilities to be
21 homeless. These addicts brought to California by the substandard rehab industry, have further
22 contributed to the public's burden by discharging addicted homeless into the community who
23 require further care and rehabilitation at the public's expense, and who commit crimes in California
24 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
25 all relevant times when they deceptively marketed their products as non-addictive that such
26 addiction would be highly difficult to overcome. Defendants knew or should have known that
27 municipalities, including San Clemente, would bear the burden of costs associated with
28 rehabilitation business of all types.

300. The role of Defendants’ deceptive marketing and distribution scheme in causing this public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have contributed to the severity of the current prescription drug abuse problem.” And in August 2016, the former U.S. Surgeon General expressly connected the “urgent health crisis” to “heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment specialists, and law enforcement and public health officials confirm that prescription opioids lawfully prescribed by doctors have fueled this epidemic.

301. Absent each Defendant’s deceptive marketing scheme and improper distribution, opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term opioid use through their deceptive marketing claims despite their knowledge of the falsity of those claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not only engaged in false advertising, they have also created or assisted in the creation of a public nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the present is part of its deceptive marketing and distribution scheme and subjects that Defendant to liability for public nuisance because there is no statute of limitations for a public nuisance claim. *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

303. Accordingly, Defendants’ conduct, both individually and collectively, has violated and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. San Clemente does not seek to limit the ability of doctors in California to prescribe opioids. San Clemente does not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, San Clemente seeks an order requiring

1 Defendants to cease their unlawful promotion and distribution of opioids, to correct their
2 misrepresentations, and to abate the public nuisance they have created. To redress and punish
3 Defendants' previous and current violations of law that cause and continue to cause harm to San
4 Clemente, Plaintiff seeks a judgment requiring Defendants to pay civil penalties, and any fees or
5 costs permitted under law.

6 304. By this action, San Clemente further seeks to recoup tax dollars spent already for
7 the consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and
8 its impact on this county and its communities, and to abate the opioid nuisance so San Clemente
9 will not be required to spend further taxpayer dollars on the epidemic and crisis wrought by
10 Defendants' wrongful conduct as alleged herein.

11 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
12 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
13 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
14 California spiked by 34% from 2011 to 2013.

15 306. Opioid abuse also contributes to a range of social problems including physical and
16 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
17 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
18 unemployment, and despair. More and more San Clemente resources are needed to combat these
19 problems. The prescription opioid crisis also diminishes San Clemente's available workforce,
20 decreases productivity, increases poverty, and requires greater governmental expenditures by San
21 Clemente.

22 307. The prescription opioid crisis has directly financially injured San Clemente. The
23 crisis has led to an increased demand for, *inter alia*, security services (such as police, EMS,
24 detention), child protective services, health services, clean-up services, and legal services. San
25 Clemente has also had to hire additional staff and expend additional resources to manage the
26 demand.

27 308. San Clemente's medical services have seen an increase in opioid-related health
28 problems among San Clemente residents, including, but not limited to, infants born with opioid-

1 related medical conditions. This has resulted in increased demand and increased expenses.

2 309. San Clemente has also suffered substantial financial damages in the form of lost
3 productivity of San Clemente employees and residents, lost economic activity, lost reputation and
4 good will, and the lost opportunity for growth. These damages have been suffered and continue to
5 be suffered directly by San Clemente.

6 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
7 their homes and their families. Some will get treatment and fewer will successfully complete it;
8 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
9 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
10 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
11 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
12 drug transactions; or dying from opioid-induced heart or neurological disease.

13 311. San Clemente also has suffered substantial financial damages in the form of lost
14 taxes paid by its residents and businesses as a result of lost earnings and productivity.

15 312. While the use of opioids has taken an enormous toll on San Clemente and its
16 residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11
17 billion in revenue for drug companies like the Defendants. Indeed, on information and belief, each
18 Defendant experienced a material increase in sales, revenue, and profits from the unlawful and
19 unfair conduct described above.

20 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
21 **Asserting Statutes of Limitations As Defenses**

22 313. Defendants' conduct has continued from the early 1990s through today and remains
23 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
24 continuous injury. The damages have not occurred all at once but have continued to occur and have
25 increased as time progresses. The tort is not completed nor have all the damages been incurred until
26 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
27 public nuisance remains unabated.

28 314. Defendants are equitably estopped from relying upon a statute of limitations defense

1 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
2 assure the public that they were undertaking efforts to comply with their obligations under the
3 controlled substances laws, all with the goal of continuing to generate profits.

4 315. For example, a Cardinal Health executive claimed that it uses “advanced analytics”
5 to monitor its supply chain, and assured the public it was being “as effective and efficient as
6 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

7 316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
8 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
9 curbing the opioid epidemic in our country.”⁸⁷

10 317. Defendants, through their trade associations, filed an amicus brief that represented
11 that Defendants took their duties seriously, complied with their statutory and regulatory
12 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

13 318. Defendants purposely concealed their wrongful conduct, including by assuring the
14 public and governmental authorities that they were complying with their obligations and were
15 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
16 behavior by providing the public with false information about opioids and have continued to use
17 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
18 is continuing to this day.

19 319. Defendants have also concealed and prevented discovery of information, including
20 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
21

22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
24 [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[7b6c1998b7a0_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html) (last accessed December 21, 2017)

25 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
Opioid Abuse, Wash. Post, (Dec. 22, 2016), available at
26 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html)
[industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html) (last accessed December 21,
27 2017).

28 ⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

1 and illegal activities.

2 320. Defendants also lobbied Congress and actively attempted to halt DEA investigations
3 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
4 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a
5 distributor's license was raised.

6 321. In addition, the Defendants fraudulently attempted to convince the public that they
7 were complying with their legal obligations and working to curb the opioid epidemic.

8 322. Because the Defendants concealed the facts surrounding the opioid epidemic, San
9 Clemente did not know if the existence or scope of the Defendants' misconduct, and could not have
10 acquired such knowledge earlier through the exercise of reasonable diligence.

11 323. Defendants intended that their false statements and omissions be relied upon,
12 including by San Clemente, and its residents.

13 324. Defendants knew of their wrongful acts and had material information pertinent to
14 their discovery, but concealed that information from the public, including San Clemente, and its
15 residents. Only Defendants knew of their widespread misinformation campaign and of their
16 repeated, intentional failures to prevent opioid diversion.

17 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
18 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
19 opioid crisis have only recently come to light.

20 326. Defendants had actual knowledge that their conduct was deceptive, and they
21 intended it to be deceptive.

22 327. San Clemente was unable to obtain vital information regarding these claims absent
23 any fault or lack of diligence on San Clemente's part.

24 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

25 **A. The Marketing Scheme**

26 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
27

28 ⁸⁹ See Higham and Bernstein, *supra* note 53.

1 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
 2 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
 3 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
 4 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
 5 long-term, chronic pain. Through their personal relationships, the members of this marketing
 6 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
 7 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
 8 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

9 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
 10 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
 11 made misleading statements and misrepresentations about opioids that downplayed the risk of
 12 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
 13 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
 14 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
 15 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
 16 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
 17 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
 18 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
 19 formulations provide a solution to opioid abuse.

20 330. The marketing scheme devised, implemented and conducted by the Manufacturer
 21 Defendants was designed to ensure that they unlawfully increased their sales and profits through
 22 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
 23 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
 24 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
 25 network as described above.

26 331. There was regular communication between the Manufacturer Defendants, Front
 27 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
 28 exchanged. Typically, the coordination, communication and payment occurred, and continues to

1 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
2 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
3 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
4 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
5 each agreed and took actions to hide the scheme and continue its existence.

6 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'
7 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
8 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
9 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
10 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
11 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
12 their members and constituents. By failing to disclose this information, Front Groups perpetuated
13 the marketing scheme, and reaped substantial benefits.

14 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
15 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
16 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
17 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
18 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
19 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
20 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
21 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
22 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
23 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
24 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
25 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

26 334. As public scrutiny and media coverage focused on how opioids ravaged
27 communities in California and throughout the United States, the Front Groups and KOLS did not
28 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous

1 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
2 using opioids for chronic pain.

3 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
4 categories of activities in furtherance of the marketing scheme. As described herein, the
5 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
6 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
7 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
8 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
9 and (d) efforts to limit prescriber accountability.

10 336. In addition to disseminating misrepresentations about the risks and benefits of
11 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
12 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
13 criticized or undermined the CDC Guidelines which represented "an important step – and perhaps
14 the first major step from the federal government - toward limiting opioid prescriptions for chronic
15 pain."

16 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
17 the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not
18 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
19 of the individuals who participated in the construction of these guidelines."

20 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
21 president, stating "that the CDC guideline makes disproportionately strong recommendations based
22 upon a narrowly selected portion of the available clinical evidence."

23 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
24 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
25 "neutral" and more "scientific" than the Manufacturer Defendants themselves. Without the work
26 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
27 scheme could not have achieved its common purpose.

28 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to

1 be prescribed and used for chronic pain throughout San Clemente, and the epidemic continues to
2 injure Plaintiff, and consume the resources of Plaintiff's emergency health services and law
3 enforcement systems.

4 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
5 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
6 in the object of the scheme, and functioned within a structure designed to effectuate the scheme's
7 purpose.

8 **B. The Distribution Scheme**

9 342. Faced with the reality that they will now be held accountable for the consequences
10 of the opioid epidemic they created, members of the industry resort to "a categorical denial of any
11 criminal behavior or intent."⁹⁰ Defendants' actions went far beyond what could be considered
12 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
13 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
14 competitive, with the common purpose and achievement of vastly increasing their respective profits
15 and revenues by exponentially expanding a market that the law intended to restrict.

16 343. Knowing that dangerous drugs have a limited place in our society, and that their
17 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
18 and addiction causes to individuals, society and governments, California enacted California
19 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
20 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
21 to detect and report such activity.

22 344. If morality and the law did not suffice, competition dictates that the Distributor
23 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
24 if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior
25 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

1 dictates that it would do so.

2 345. The Distributor Defendants' scheme required the participation of all. If any one
3 member broke rank, its compliance activities would highlight deficiencies of the others, and the
4 artificially high quotas they maintained through their scheme would crumble. But, if all the
5 members of the enterprise conducted themselves in the same manner, it would be difficult for state
6 authorities or the DEA to go after any one of them. Accordingly, through the connections they
7 made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the
8 Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly,
9 in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting
10 Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the
11 Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance
12 Guidelines, which recognize these Defendants' duties under the law, as illustrated by the
13 subsequent industry-wide enforcement actions and consent orders issued after that time, none of
14 them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult
15 to find the right balance between proactive anti-diversion efforts while not inadvertently limiting
16 access to appropriately prescribed and dispensed medications." Yet, the Distributor Defendants
17 apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure
18 the largest possible financial return.

19 346. As described above, at all relevant times, the Distributor Defendants conspired
20 together for the purpose of unlawfully increasing sales, revenues and profits. In support of this
21 common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard
22 their statutory duties to identify, investigate, halt and report suspicious orders of opioids and
23 diversion of their drugs into the illicit market so that those orders would not result in a decrease, or
24 prevent an increase in, the necessary quotas.

25 347. At all relevant times, as described above, the Distributor Defendants exerted control
26 over, conducted and/or participated in distribution scheme by fraudulently claiming that they were
27 complying with their duties under California law to report suspicious orders and to maintain
28 systems to detect and report such activity.

348. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators' ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the "Ensuring Patient Access and Effective Drug Enforcement Act."⁹¹

349. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

350. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

351. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what

⁹¹ HDMA is Now the Healthcare Distribution Alliance, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 doctors wanted to believe – namely, that opioids represented a means of relieving their patients’
2 suffering and of practicing medicine more compassionately.

3 352. Each Defendant’s conduct and role in creating or assisting in the creation of the
4 public health crisis now plaguing California is directly relevant to the amount of the civil penalties
5 to be awarded under California Business & Professions Code § 17536.

6 353. As a members of the boards of various Purdue entities, the Sacklers oversaw all
7 aspects of Purdue’s marketing and promotion of opioid products. As board members who were
8 personally active in directing Purdue’s operations, the Sackler Defendants knew, or should have
9 known, of Purdue’s deceptive marketing tactics of opioid products.

10 354. The Sackler Defendants also were aware of specific examples of deceptive
11 marketing through receipt of call note reviews in their capacities as board members. On information
12 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
13 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
14 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

15 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
16 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
17 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
18 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

19 356. By 2006, prosecutors at the United States Department of Justice found damning
20 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
21 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
22 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
23 events and side effects than other pain medications.

24 357. As members of the family that owns Purdue, the Sackler Defendants personally
25 benefitted from the success of OxyContin. At various points, as directors, they approved the
26 distribution of funds from Purdue to shareholders, including themselves and their extended family.

27 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
28 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.

1 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
2 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
3 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
4 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
5 the opioid related liabilities of the companies from which they were transferred.

6 359. Plaintiff is informed and believes that due to the billions of dollars in profits that
7 have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to
8 satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced
9 litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the
10 Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly
11 profited and received the benefits of that wrongdoing.

12 **VII. CAUSES OF ACTION**

13 **FIRST CAUSE OF ACTION**

14 **(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)**

15 360. Plaintiff realleges and incorporates herein by reference each and every allegation in
16 paragraphs 1 through 359 above as if set forth fully herein.

17 361. California Civil Code § 3479 provides that “anything which is injurious to health ...
18 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
19 interfere with the comfortable enjoyment of life or property ... is a nuisance.”

20 362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at
21 the same time an entire community or neighborhood, or any considerable number of persons,
22 although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

23 363. California Civil Code § 3490 states that “no lapse of time can legalize a public
24 nuisance, amounting to an actual obstruction of public right.”

25 364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought
26 by San Clemente to abate the public nuisance created by the Defendants.

27 365. Each Defendant, acting individually and in concert, has created or assisted in the
28 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment

1 of life and property of entire communities or neighborhoods or of any considerable number of
2 persons in San Clemente in violation of California Civil Code §§ 3479 and 3480.

3 366. The public nuisance is substantial and unreasonable. Defendants' actions caused and
4 continue to cause the public health epidemic described above in San Clemente, and that harm
5 outweighs any offsetting benefit.

6 367. Defendants knew and should have known that their promotion and distribution of
7 opioids was false and misleading and that their deceptive marketing scheme and other unlawful,
8 unfair, and fraudulent actions would create or assist in the creation of the public nuisance—i.e., the
9 opioid epidemic.

10 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
11 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
12 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
13 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
14 so widespread, and the opioid epidemic that now exists would have been averted or much less
15 severe.

16 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
17 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
18 can be abated.

19 370. Each Defendant is liable for public nuisance because its conduct at issue is
20 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
21 endangers the safety, health, morals, comfort, or repose of a considerable number of people in San
22 Clemente. Defendants' conduct is also indecent or offensive to the senses, and constitutes an
23 obstruction to the free use of property sufficient to constitute an interference with the people of San
24 Clemente's comfortable enjoyment of life or property.

25 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
26 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
27 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
28 unreasonable interference with San Clemente and its residents' public rights, including, but not

1 limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to
2 be free from disturbance and reasonable apprehension of danger to person or property.

3 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
4 interfered with San Clemente and its residents' public rights by, *inter alia*, engaging in a promotion
5 and marketing scheme that pushed the use of opioids for indications not federally approved, and by
6 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
7 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
8 Defendants failed to comply with federal law.

9 373. Defendants have also unlawfully and intentionally distributed opioids or caused
10 opioids to be distributed within and without San Clemente absent effective controls against
11 diversion. Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures
12 to maintain effective controls against diversion include Defendants' failure to effectively monitor
13 for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

14 374. Defendant's unreasonable interference with San Clemente residents' public rights
15 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
16 expenditures to combat and address these harms. These damages have been suffered and continue
17 to be suffered directly by San Clemente and its residents.

18 375. Defendants' actions have also created a palpable climate of fear, distress,
19 dysfunction and chaos among residents of San Clemente where opioid diversion, abuse, and
20 addiction are prevalent and where diverted opioids are used frequently. Specifically, Defendants
21 conduct has caused, among other things, (a) routine separation of children from their parents who
22 have fallen victim to easy access to opioids and/or related crime; (b) children to have easy access
23 and to become addicted to opioids; (c) residents to endure both the emotional and financial costs of
24 caring for loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of
25 public spaces and property; (e) property crimes throughout San Clemente; (f) employers to lose the
26 value of productive and healthy employees; (g) increased public health and safety costs; (h) a
27 reduction in potential property values within San Clemente; and (i) a decrease in tax revenues for
28 San Clemente.

1 376. The impact of Defendants' conduct on San Clemente is of a continuing nature.
2 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

3 377. Defendants knew or should have known that their actions would lead to the national
4 opioid epidemic and to the resulting injuries to the public rights of San Clemente.

5 378. San Clemente has sustained a special and peculiar injury because its damages
6 include, *inter alia*, health service expenditures, public safety expenditures, payment of opioid
7 addiction treatment, decreased tax revenues, a reduction in potential property values, and other
8 costs related to opioid addiction treatment and overdose prevention.

9 379. The externalized risks associated with Defendants' nuisance-creating conduct as
10 described herein greatly exceed the internalized benefits.

11 380. Defendants' actions are a direct and proximate contributing cause of the opioid
12 epidemic and the injuries to the public rights of San Clemente and its residents.

13 381. Defendants, individually and collectively, are at the very least, a substantial factor
14 in causing the national opioid epidemic and of the injuries to San Clemente and its residents.

15 382. The injuries to the public rights of San Clemente and its residents are indivisible
16 injuries.

17 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
18 if unabated, will continue to cause an unreasonable interference with public rights of San Clemente
19 and its residents.

20 384. Defendants' conduct is ongoing and persistent, and San Clemente seeks all damages
21 flowing from Defendants' conduct. San Clemente seeks economic losses (direct, incidental, and/or
22 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
23 above. San Clemente does not seek damages for the wrongful death, physical personal injury, or
24 emotional distress caused by Defendants' actions.

25 385. Pursuant to Code of Civil Procedure § 731, San Clemente requests an order
26 providing for abatement of the public nuisance that Defendants created or assisted in the creation
27 of, and enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.
28

SECOND CAUSE OF ACTION
(Fraud – Against All Defendants)

386. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 385 above as if set forth fully herein.

387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set forth herein

388. The Defendants made fraudulent misrepresentations and omissions of material fact. Defendants' knowing deceptions during the relevant period, more fully described in this Complaint, were intended to induce reliance.

389. Those misrepresentations and omissions were known to be untrue by the Defendants, or were recklessly made.

390. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the dangers of abuse, and the risks of addiction.

391. As alleged herein, Defendants made false statements and/or omissions regarding their compliance with state law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements. Defendants also failed to disclose the prevalence of diversion of controlled substances, including opioids, within San Clemente.

392. Defendants made those misrepresentations and omissions in an intentional effort to deceive San Clemente and its residents, despite the Defendants' knowledge of the dangers of such use of prescription opioids.

393. In addition and independently, Defendants had a duty not to deceive Plaintiff because Defendants had in their possession unique material knowledge that was unknown, and not knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

394. The Defendants continued making those misrepresentations, and failed to correct those material omissions, despite repeated regulatory settlements and publications demonstrating the false and misleading nature of the Defendants' omissions and/or claims.

1 395. While Defendants had a duty to disclose the above-referenced material facts, they
2 nevertheless concealed them. These false representations and concealed facts were material to the
3 conduct and actions at issue. Defendants made these false representations and concealed facts with
4 knowledge of the falsity of their representations and did so with the intent of misleading San
5 Clemente, its residents, the public, and persons on whom these entities relied.

6 396. Defendants intended and had reason to expect under the operative circumstances
7 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
8 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
9 and that these entities would act or fail to act in reasonable reliance thereon.

10 397. San Clemente, its residents, and others, did in fact rightfully, reasonably, and
11 justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

12 398. For instance, doctors, including those serving San Clemente and its residents, relied
13 on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
14 Patients, including residents of San Clemente, relied on the Defendants' misrepresentations and
15 omissions in taking prescription opioids for chronic pain relief.

16 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
17 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
18 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
19 effective response to the opioid crisis.

20 400. Defendants' misconduct alleged in this case is ongoing and persistent.

21 401. San Clemente has experienced an unprecedented opioid addiction and overdose
22 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
23 services, and lost productivity to San Clemente's workforce.

24 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
25 result of Defendants' fraudulent conduct.

26 403. As a direct and foreseeable consequence of Defendants' fraud, San Clemente has
27 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
28 opioid addiction treatment and its secondary consequences in excess of those San Clemente would

1 have otherwise incurred.

2 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
3 fraudulent, entitling San Clemente to punitive damages.

4 **THIRD CAUSE OF ACTION**
5 **(Negligence – Against All Defendants)**

6 405. Plaintiff realleges and incorporates herein by reference each and every allegation in
7 paragraphs 1 through 404 above as if set forth fully herein.

8 406. To establish actionable negligence in California, Plaintiff must show a duty, a breach
9 of that duty, and injury resulting proximately therefrom.

10 407. Defendants have a duty to exercise reasonable care under the circumstances, in light
11 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
12 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
13 and still have, a duty to exercise reasonable care to prevent the threatened harm.

14 408. In addition, Defendants had a duty not to breach the standard of care established
15 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
16 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
17 to abuse, and to develop and maintain systems to detect and report such activity.

18 409. Defendants voluntarily undertook a legal duty to prevent the diversion of
19 prescription opioids by engaging in the distribution of prescription opioids and by making public
20 promises to prevent the diversion of prescription opioids.

21 410. Defendants knew of the serious problem posed by prescription opioid diversion and
22 were under a legal obligation to take reasonable steps to prevent diversion.

23 411. Defendants knew of the highly addictive nature of prescription opioids and of the
24 high likelihood of foreseeable harm to patients and communities, including San Clemente, from
25 prescription opioid diversion.

26 412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
27 in accordance with applicable standards of conduct in advertising, marketing, selling, and
28 distributing opioid products in a safe manner to minimize the risk of addiction in patients and

1 resultant harm to those patients, their families and their communities, and to taxpayers and
 2 municipal government such as San Clemente which must incur enormous expenditures for
 3 prevention, treatment, emergency response and law enforcement costs and other foreseeable costs
 4 related to the need to address the consequences of a large number of residents that become addicted
 5 to opioids as a result of Defendants' conduct.

6 413. As described throughout the Complaint, Defendants breached their duties to
 7 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
 8 monitor for, failing to report, and filling highly suspicious orders time and again.

9 414. As described throughout the Complaint, in language expressly incorporated herein,
 10 Defendants misrepresented their compliance with their duties under the law and concealed their
 11 noncompliance and shipments of suspicious orders of opioids to San Clemente and destinations
 12 from which they knew opioids were likely to be diverted into San Clemente, in addition to other
 13 misrepresentations alleged and incorporated herein.

14 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
 15 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
 16 purported benefits of long-term use of opioids for the treatment of chronic pain.

17 416. Manufacturer Defendants knew or should have known, that their affirmative
 18 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
 19 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
 20 representatives, and internal documents, should have put them on notice that such harm was not
 21 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
 22 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
 23 and the public.

24 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
 25 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

26 418. Defendants' misconduct alleged in this case is ongoing and persistent.

27 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
 28 acted with a conscious disregard for the rights and safety of other persons, and said actions had a

1 great probability of causing substantial harm.

2 420. As is described throughout this Complaint, Defendants acted without even slight
3 diligence or scant care, and with indifference, and were negligent in a very high degree,
4 disregarding the rights and safety of other persons, and said actions have a great probability of
5 causing substantial harm.

6 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
7 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
8 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
9 minimize the risk of addiction in patients and resultant harm to those patients, their families and
10 their communities, and to taxpayers and municipal government such as San Clemente, including,
11 but not limited to, the following:

- 12 a. Foreseeability of harm to San Clemente: Defendants were aware or reasonably
13 should have been aware of the risk of addiction of a large number of patients in
14 places such as San Clemente, and need for their care and treatment and in
15 handling other consequences of their addiction and that such costs would be
16 borne by local governments such as San Clemente;
- 17 b. Degree of certainty San Clemente suffered harm: San Clemente has suffered
18 enormous harm and costs in addressing treatment of addicted patients, including
19 but not limited to expenditures for prevention, treatment, emergency response
20 and law enforcement costs and other foreseeable costs related to the need to
21 address the consequences of a large number of residents that become addicted
22 to opioids as a result of Defendants' conduct;
- 23 c. Closeness of connection between San Clemente's harm: The explosion of opioid
24 addiction and the presence of opioid addicted patients in San Clemente as a
25 result of Defendants' conduct has resulted in expenditures directly for
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1 prevention, treatment, emergency response and law enforcement costs and other
2 foreseeable costs related to the need to address the consequences;

3 d. Moral blame attached to Defendants' conduct: Defendants' knew or should have
4 known that their wrongful conduct, actions and omissions would result in an
5 explosion of patients who would become addicted to opioids, and that a vast
6 opioid epidemic would result from the prescription of opioids to tens of millions
7 of patients nationwide, including within San Clemente, and that the costs would
8 be borne by the state, county and municipal local governments, while
9 Defendants profited tens of billions of dollars collectively from the widespread
10 use of prescription opioid products;

11 e. Policy of preventing future harm: As a direct and foreseeable result of
12 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
13 to occur on a vast scale both nationally and locally in places such as San
14 Clemente resulting in tremendous harm and cost to the patients, their families
15 and the communities in dealing with this epidemic and crisis, and there is a need
16 to ensure that the costs of such wrongful conduct is borne by Defendants so that
17 parties contemplating such or similar conduct in the future know they will be
18 held responsible for such harm;

19 f. Extent of burden to Defendants: There is no burden to Defendants in that state
20 and other law precludes them from engaging in the conduct alleged herein, and
21 there is no burden from precluding Defendants from profiting from their
22 wrongful conduct and operating within the confines of the law in advertising,
23 marketing, selling and distributing opioid products in a safe manner to minimize
24 the risk of addiction in patients and resultant harm to those patients, their
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families and their communities, and to taxpayers and municipal government such as Plaintiff San Clemente; and

g. Consequences to the community of imposing a duty to exercise care with resulting liability for breach: Imposing a duty to not engage in Defendants' wrongful conduct of advertising, marketing, selling and distributing opioid products in an unsafe manner would minimize the risk of addiction in patients, and liability for a breach of this duty would benefit communities such as San Clemente in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the country and the nation.

422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled substances laws cited above.

423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for security services, emergency, health, prosecution, corrections, and rehabilitation services, as well as the cost of opioid addiction treatment paid by San Clemente.

424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

425. Defendants' breaches of their duty of care foreseeably and proximately caused damage to San Clemente and its residents.

426. Manufacturer Defendants are guilty of negligence per se in that the Defendants violated applicable California laws, statutes, and regulations, in the manner in which they advertised, marketed, sold and distributed opioid products.

427. Distributor Defendants are guilty of negligence per se in that the Defendants violated California laws, statutes, and regulations designed to protect Plaintiff from the harms it has

1 suffered, including, but not limited to, the following:

- 2 a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug,
3 and Cosmetic Laws, California Health & Safety Code § 110390;
- 4 b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that
5 had been falsely advertised in violation of the Sherman Food, Drug, and
6 Cosmetic Laws, California Health & Safety Code § 110395;
- 7 c. Defendants received in commerce opioids that were falsely advertised or
8 delivered or proffered for delivery opioids that were falsely advertised in
9 violation of the Sherman Food, Drug, and Cosmetic Laws, California Health &
10 Safety Code § 110400;
- 11 d. Defendants failed to report all sales of dangerous drugs subject to abuse in
12 excess of the amounts set by the California State Board of Pharmacy in violation
13 of 16 C.C.R. §1782;
- 14 e. Defendants failed to track and report all purchases that exceeded prior purchases
15 by long-term care facilities or similar customers by a factor of 20 percent in
16 violation of California Business & Professions Code § 4164; and
- 17 f. Defendants failed to report all suspicious orders placed by California pharmacies
18 or wholesalers after January 1, 2018 as required by California Business &
19 Professions Code § 4169.1.

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23 428. As a direct and proximate consequence of Defendants' negligent acts, omissions,
24 misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic,
25 including in San Clemente. San Clemente, as a further direct and proximate consequence and result
26 thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs
27 for treatment of opioid addicted patients, emergency response costs, law and regulatory
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1 enforcement costs, and measures for prevention of further opioid abuse and addiction.

2 429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
3 fraudulent, entitling San Clemente to punitive damages.

4 **FOURTH CAUSE OF ACTION**
5 **(Unjust Enrichment – Against All Defendants)**

6 430. Plaintiff realleges and incorporates herein by reference each and every allegation in
7 paragraphs 1 through 429 above as if set forth fully herein.

8 431. As an expected and intended result of their conscious wrongdoing as set forth in this
9 Complaint, Defendants have profited and benefited from the increase in the distribution and
10 purchase of opioids within San Clemente, including from opioids foreseeably and deliberately
11 diverted within and into San Clemente.

12 432. Plaintiff has expended substantial amounts of money in an effort to remedy or
13 mitigate the societal harms caused by Defendants' conduct.

14 433. These expenditures include, but are not limited to, the provision of emergency
15 medical services and treatment services to people who use opioids.

16 434. These expenditures have helped sustain Defendants' businesses.

17 435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
18 externalities: the cost of the harms caused by Defendants' improper distribution practices.

19 436. Defendants were aware of these obvious benefits, and their retention of the benefit
20 is unjust.

21 437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
22 benefited from those payments because they allowed them to continue providing customers with a
23 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
24 Defendants obtained enrichment they would not otherwise have obtained. Because of their
25 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
26 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
27 lacks a remedy provided by law.

28 438. Defendants' misconduct alleged in this case is ongoing and persistent.

439. Defendants have unjustly retained benefits to the detriment of San Clemente, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

440. San Clemente is entitled to restitution and disgorgement from Defendants in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
(Civil Conspiracy – Against All Defendants)

441. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 440 above as if set forth fully herein.

442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into California and San Clemente.

443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into California and San Clemente.

444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the conspiracy by increasing the volume of opioid sales in the United States through creating a market for non-medical use of opioids of epidemic proportions.

446. Many of the Manufacturing Defendants are members, participants, and/or sponsors of the Healthcare Distribution Alliance ("HDA"), and have been since at least 2006, and utilized the HDA to give further assistance to the conspiracy.

447. The Manufacturing Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct

1 to commit acts of fraud.

2 449. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had
3 to agree to implement similar tactics.

4 450. By intentionally refusing to report and halt suspicious orders of their prescription
5 opioids, Defendants engaged in a fraudulent scheme.

6 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
7 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
8 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
9 and were actually being diverted into the market of non-medical use.

10 452. Defendants further unlawfully marketed opioids in California and San Clemente in
11 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
12 dissemination of false and misleading information about the safety and efficacy of long-term opioid
13 use through, among other things: (a) the use of "Front Groups" that appeared to be independent of
14 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
15 continuing medical education ("CME") programs controlled and/or funded by the Defendants; (d)
16 hiring and deploying so-called "key opinion leaders" or "KOLs" who were paid by the Defendants
17 to promote their message; and (e) the "detailing" activities of the Defendants' sales forces, which
18 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
19 physicians lacking the expertise of pain care specialists.

20 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
21 unbiased, independent patient-advocacy and professional organizations in order to disseminate
22 patient education materials, a body of biased and unsupported scientific "literature," and "treatment
23 guidelines" that promoted the Defendants' false messages.

24 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
25 influence prescribers' habits by promoting the Defendants' false message through, among other
26 things, writing favorable journal articles and delivering supportive CMEs as if they were
27 independent medical professionals, thereby further obscuring the Defendants' role in the
28 conspiracy.

1 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
2 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
3 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
4 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
5 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
6 were industry-friendly and would work together with the Defendants to advance the conspiracy.

7 456. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this
8 Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes.
9 Such allegations are specifically incorporated herein.

10 457. Defendants acted with a common understanding or design to commit unlawful acts,
11 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
12 proximately caused the injuries alleged herein.

13 458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
14 reasonable or lawful excuse.

15 459. Defendants conduct in furtherance of the conspiracy described herein was not mere
16 parallel conduct because each Defendant acted directly against their commercial interests in not
17 reporting the unlawful distribution practices of their competitors to the authorities, which they had
18 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
19 actual or tacit agreement between the Defendants that they would not report each other to the
20 authorities so they could all continue engaging in their unlawful conduct.

21 460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
22 thereof, caused the direct and foreseeable losses alleged herein.

23 461. Defendants' misconduct alleged in this case is ongoing and persistent.

24 462. As a result of Defendants' conspiracy, San Clemente is entitled to compensatory
25 damages in an amount to be proved at trial.

26 463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
27 fraudulent, entitling San Clemente to punitive damages.
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SIXTH CAUSE OF ACTION**(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

464. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 463 above as if set forth fully herein.

465. California Business & Professions Code § 17500 makes it unlawful for a business to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning ... real or personal property ... which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.”

466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign designed to disseminate false or misleading statements designed to promote the belief that opioid drugs could safely be used in a non-addictive manner.

467. By way of example, Actavis’s predecessor created a patient brochure for Kadian in 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

468. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is “less likely if you have never had an addiction problem.”

469. Cephalon and Purdue sponsored research and publications that falsely and deceptively stated opioids did not have “ceiling dose.”

470. Purdue created websites, available to the public that instructed patients to seek new medical providers out if their current provider would not increase their dose.

471. Defendants’ false and deceptive advertising practices resulted in increased opioid dosages being prescribed to San Clemente’s residents, increasing the incidence of opioid addiction and overdose in San Clemente.

472. Distributor Defendants also repeatedly omitted material information and/or falsely represented that they were effectively preventing diversion and were monitoring, reporting, and preventing suspicious orders.

473. As alleged above, Defendants’ statements about the risks associated with opioid use

1 were not supported by or were contrary to the scientific evidence.

2 474. As alleged above, each Defendant's conduct, separately and collectively, was likely
3 to deceive California payors who purchased or covered the purchase of opioids.

4 475. San Clemente seeks restitution and injunctive relief under California Business &
5 Professions Code § 17535.

6 476. San Clemente also seeks an order assessing a civil penalty of two thousand five
7 hundred dollars (\$2,500) against Defendants for each violation of California's False Advertising
8 Law pursuant to California Business & Professions Code § 17536.

9 **SEVENTH CAUSE OF ACTION**

10 **(Negligent Failure to Warn—Against Manufacturer Defendants)**

11 477. Plaintiff realleges and incorporates herein by reference each and every allegation in
12 paragraphs 1 through 476 above as if set forth fully herein.

13 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
14 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
15 adequately warning the medical profession about the risk of addiction from the use of opioid
16 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
17 cancel out, and render meaningless any written warnings given about the risk of addiction from the
18 use of opioid products.

19 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
20 to adequately warn the medical profession about the risk of addiction from the use of opioid
21 products, including by overpromoting and over-marketing opioid products in a manner so as to
22 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
23 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
24 products in situations and for patients who should not have been using those drugs or should have
25 used them only as a last resort before other means were used or other less addictive and dangerous
26 drugs were prescribed.

27 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
28 and overpromoting and over-marketing the use of prescription opioid products, there is now a

1 national opioid addiction epidemic, including in San Clemente. The People, as a further direct and
 2 proximate consequence and result thereof, sustained injuries and damages including but not limited
 3 to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs,
 4 law and regulatory enforcement costs, opioid disposal programs, and measures for prevention of
 5 further opioid abuse and addiction.

6 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
 7 fraudulent, entitling San Clemente to punitive damages.

8 **EIGHTH CAUSE OF ACTION**
 9 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler**
 10 **Defendants)**

11 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
 12 paragraphs 1 through 481 above as if set forth fully herein.

13 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
 14 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
 15 possess a right to payment from Purdue.

16 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
 17 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
 18 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
 19 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

20 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
 21 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
 22 including Plaintiff.

23 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
 24 them pursuant to California Civil Code § 3439.04(a)(1).

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NINTH CAUSE OF ACTION

(Civil Conspiracy – Against Purdue and Sackler Defendants)

487. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 486 above as if set forth fully herein.

488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection of its judgment against Purdue entered in this action.

489. After the Sackler Defendants became aware in or about 1999 that Purdue faced potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other opioid-containing medications via distributions from Purdue to shareholders, including the Sackler Defendants and their extended family.

490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.

491. Purdue and the Sackler Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and proximately caused the injuries alleged herein.

492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the judgment entered in this action.

494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to compensatory damages in an amount to be proved at trial.

495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, San Clemente and the People respectfully request judgment in their favor granting the following relief:

- a) Entering Judgment in favor of San Clemente and the People in a final order against each of the Defendants;
- b) An award of actual and consequential damages in an amount to be determined at trial;
- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an "abatement fund" for the purposes of abating the public nuisance;

- 1 n) An order awarding the damages caused by the opioid epidemic, including, *inter*
2 *alia*, (a) costs for providing medical care, additional therapeutic and prescription
3 drug purchases, and other treatments for patients suffering from opioid-related
4 addiction or disease, including overdoses and deaths; (b) costs for providing
5 treatment, counseling, and rehabilitation services; (c) costs for providing treatment
6 of infants born with opioid-related medical conditions; (d) costs for providing care
7 for children whose parents suffer from opioid-related disability or incapacitation;
8 (e) costs associated with public safety and security services relating to the opioid
9 epidemic; (f) costs for cleanup of public areas;
- 10 o) An order that the transfers from Purdue to the Sackler Defendants be set aside to
11 the extent necessary to satisfy Plaintiff's judgment against Purdue herein;
- 12 p) An order that an order pendente lite be granted Plaintiff enjoining and restraining
13 the Sackler Defendants and their representatives, attorneys, servants, and agents
14 from selling, transferring, conveying, assigning, or otherwise disposing of any of
15 the property transferred to them by Purdue;
- 16 q) An order that the judgment granted herein be declared a lien against the property
17 transferred to the Sackler Defendants by Purdue;
- 18 r) An award of punitive damages;
- 19 s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- 20 t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to
21 California Code of Civil Procedure § 1021.5;
- 22 u) Pre- and post-judgment interest as allowed by law; and
- 23 v) Any other relief deemed just, proper, and/or equitable.

24 **PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE**

25 Dated: March 27, 2019

26 **ROBINS KAPLAN LLP**

27 By: 

28 Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

EXHIBIT F

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment
 form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF IRVINE; and THE
(LO ESTÁ DEMANDANDO EL DEMANDANTE): PEOPLE OF THE STATE
OF CALIFORNIA, by and through Irvine City Attorney
 Jeffrey Melchin

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
 (El nombre y dirección de la corte es):

San Francisco County Superior Court
 Civic Center Courthouse
 400 McAllister Street
 San Francisco, CA 94102-4515

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800
 Lucas A. Messenger, Bar No. 217645
 ROBINS KAPLAN LLP
 Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

CLERK OF THE COURT

Clerk, by

(Secretario)

DE LA VEGA-NAVARRO, Rossaly, Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
 2. ☐ as the person sued under the fictitious name of (specify):

3. ☐ on behalf of (specify):

under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)

- ☐ other (specify):
 4. ☐ by personal delivery on (date):

(SEAL)

SUM-200(A)

SHORT TITLE: City of Irvine, et al. v. Purdue Pharma
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

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of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN FRANCISCO

CITY OF IRVINE; and THE PEOPLE OF
THE STATE OF CALIFORNIA, by and
through Irvine City Attorney Jeffrey
Melching,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

ENDORSED
FILED
Superior Court of California
County of San Francisco

MAR 28 2019

CLERK OF THE COURT
BY: ROSSALY DE LA VEGA
Deputy Clerk

Case No.

CGC-19-574866

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;
8. FRAUDULENT TRANSFER; and

9. CIVIL CONSPIRACY

SACKLER, an individual; IRENE SACKLER LEFCOURT, an individual; BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual; DAVID A. SACKLER, an individual; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC.; ACTAVIS LLC; INSYS THERAPEUTICS, INC.; MALLINCKRODT, PLC; MALLINCKRODT, LLC; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; MCKESSON CORPORATION; and DOES 1-100, inclusive,

Defendants.

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	2
A.	The Plaintiffs.....	2
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	9
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	11
IV.	GENERAL FACTUAL ALLEGATIONS.....	11
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Irvine Through Illicit Channels.....	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Irvine Through Illicit Channels.....	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Irvine	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	83
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff City of Irvine (hereinafter, “Irvine”) has been particularly hard hit, causing Irvine to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. Irvine, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California (the “People,” and together with Irvine, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants' efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. Irvine has seen increased costs of, among other things, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (e) public safety connected to the opioid epidemic within Irvine, including police, emergency response services, and

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 detention centers; (f) increased burden on Irvine's code enforcement programs; (g) re-education of
 2 doctors and patients about the appropriate use of opioids; and (h) extensive clean-up of public parks,
 3 spaces, and facilities. At the same time, Irvine has seen a reduction to tax revenues caused by the
 4 epidemic created by the Defendants. Almost every citizen of Irvine has been affected. The resulting
 5 damage to Irvine was directly and foreseeably caused by Defendants' actions.

6 7. These increased costs could have been—and should have been—prevented by the
 7 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
 8 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
 9 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
 10 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
 11 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
 12 protecting opioids from theft, misuse, and diversion.

13 8. Instead of acting with reasonable care and in compliance with their legal duties,
 14 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
 15 process.

16 9. At the same time, Defendants flooded the market with false statements designed to
 17 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
 18 claims were false.³

19 10. Defendants' actions have not only caused significant costs, but have also created a
 20 palpable climate of fear, distress, dysfunction and chaos among Irvine residents where opioid
 21 diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

22 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
 23 and/or unlawful conduct.

24 **II. THE PARTIES**

25 **A. The Plaintiffs**

26 12. Irvine, California, by and through its attorneys hereto and its City Attorney, hereby

27
 28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

1 brings this action this action on its own behalf for injuries suffered and on behalf of the People of
2 the State of California (“People”) to protect the public from false and misleading advertising,
3 fraudulent acts, negligent acts, and a public nuisance.

4 13. Irvine has standing to recover damage incurred because of Defendants’ actions and
5 omissions. Irvine has standing to bring actions including, *inter alia*, public nuisance claims asserted
6 under state law.

7 **B. The Manufacturer Defendants**

8 14. The Manufacturer Defendants are defined below. At all relevant times, the
9 Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of
10 commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported
11 to inform prescribers and users regarding the benefits and risks associated with the use of
12 prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have
13 manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion
14 and report suspicious orders.

15 15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of
16 Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business
17 in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation
18 with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma
19 Inc., and The Purdue Frederick Company are referred to collectively as “Purdue”).

20 16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin,
21 MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States,
22 including California. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual sales
23 of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006
24 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
25 (painkillers).

26 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
27

28 ⁴ Long-acting or extended release (“ER” or “ER/LA”) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (“IR”) opioids, last for approximately 4-6 hours.

California, acting by and through the California Attorney General, based principally on Purdue's direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M) and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its promotional and marketing practices regarding OxyContin at any time up to and including May 8, 2007. The People, however, do assert claims arising under California law independent of the Purdue Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"), which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the Raymond Sackler Trust.

20. Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in California, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for covering certain co-pay costs.

29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s USA’s sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd. operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in

1 New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now
 2 known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of
 3 business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen
 4 Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in
 5 Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than
 6 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's
 7 products. Upon information and belief, J&J controls the sale and development of Janssen
 8 Pharmaceutical's products and Janssen's profits inure to J&J's benefit. (together, Janssen
 9 Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc.,
 10 and J&J are referred to as "Janssen").

11 31. Janssen manufactures, promotes, sells, and distributes drugs in the United States,
 12 including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted
 13 for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold
 14 the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172
 15 million in sales in 2014.

16 32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal
 17 place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly
 18 owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal
 19 place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals
 20 Inc. are referred to collectively as "Endo").

21 33. Endo develops, markets, and sells prescription drugs, including the opioids
 22 Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In
 23 2012, opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion. Opana ER
 24 yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo's total
 25 revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,
 26 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
 27 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
 28 International Trade Co., is registered to do business in California with the California Secretary of

1 State.

2 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
3 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
4 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
5 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
6 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
7 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
8 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
9 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
10 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
11 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
12 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
13 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
14 Laboratories, Inc. are referred to as “Actavis”).

15 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
16 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
17 in the United States, including California. Actavis acquired the rights to Kadian from King
18 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
19 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
20 California Secretary of State.

21 36. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
22 principal place of business located in Chandler, Arizona.

23 37. Insys manufacturers, promotes, sells, and distributes opioids. Insys’ principal source
24 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
25 United States, including California. Subsys was indicated by the FDA for the treatment of
26 breakthrough cancer pain that other opioids could not eliminate.

27 38. In May 2018, an Insys sales representative admitted to taking part in a scheme to
28 bribe physicians with purported speaking fees for marketing and education events in exchange for

1 them prescribing Subsys for off-label uses.

2 39. Insys' founder and several other former Insys executives were recently indicted by
3 federal prosecutors on racketeering charges, alleging that these individuals approved and fostered
4 fraudulent behavior against insurance companies and also conspired to bribe practitioners in various
5 states. Insys Group is registered to do business in California with the California Secretary of State.

6 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
7 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
8 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
9 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
10 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt").

11 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
12 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
13 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
14 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
15 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
16 Products are registered to do business in California with the California Secretary of State.

17 42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Insys, and
18 Mallinckrodt are the "Manufacturer Defendants."

19 **C. The Distributor Defendants**

20 43. CARDINAL HEALTH, INC. ("Cardinal") is a publicly traded company
21 incorporated under the laws of Ohio and with a principal place of business in Ohio.

22 44. Cardinal distributes prescription opioids to providers and retailers, including in
23 California. Cardinal has engaged in consensual commercial dealings with Irvine and its residents,
24 and has purposefully availed itself of the advantages of conducting business with and within Irvine.
25 Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health
26 127, and Cardinal Health 201 are registered to do business in California with the California
27 Secretary of State.

28 45. AMERISOURCEBERGEN CORPORATION ("AmerisourceBergen") is a publicly

1 traded company incorporated under the laws of Delaware and with a principal place of business in
2 Pennsylvania.

3 46. AmerisourceBergen distributes prescription opioids to providers and retailers,
4 including in California. AmerisourceBergen has engaged in consensual commercial dealings with
5 Irvine and its residents, and has purposefully availed itself of the advantages of conducting business
6 with and within Irvine. AmerisourceBergen is in the chain of distribution of prescription opioids.
7 AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation,
8 AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are
9 registered to do business in California with the California Secretary of State.

10 47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company
11 incorporated under the laws of Delaware and with a principal place of business in San Francisco,
12 California.

13 48. McKesson distributes prescription opioids to providers and retailers, including in
14 California. McKesson has engaged in consensual commercial dealings with Irvine and its residents,
15 and has purposefully availed itself of the advantages of conducting business with and within Irvine.
16 McKesson is in the chain of distribution of prescription opioids. McKesson Corporation is
17 registered to do business in California with the California Secretary of State.

18 49. The data which reveals and/or confirms the identity of the other wrongful opioid
19 distributor is hidden from public view in the DEA’s confidential ARCOS database. *See Madel v.*
20 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
21 voluntarily disclose the data necessary to identify with specificity the transactions which will form
22 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

23 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
24 market share for the distribution of prescription opioids. The “Big 3” are Fortune 500 corporations
25 listed on the New York Stock Exchange and their principal business consists of the nationwide
26 wholesale distribution of prescription drugs. *See Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12
27 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
28 predecessors). Each has been investigated and/or fined by the DEA for the failure to report

1 suspicious orders. Irvine has reason to believe each has engaged in unlawful conduct which resulted
 2 in the distribution, dispensing, and diversion of prescription opioids into Irvine. Irvine names each
 3 of the “Big 3” herein as defendants and places the industry on notice that Irvine is acting to abate
 4 the public nuisance plaguing its community. Distributor Defendants have had substantial contacts
 5 and business relationships with the People. Distributor Defendants have purposefully availed
 6 themselves of business opportunities within Irvine.

7 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the “Distributor
 8 Defendants.”

9 **D. The Doe Defendants**

10 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
 11 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
 12 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
 13 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
 14 is informed and believes, and on such information and belief alleges, that each of the Defendants
 15 named as a DOE is responsible in some manner for the events and occurrences alleged in this
 16 Complaint and is liable for the relief sought herein.

17 **III. JURISDICTION AND VENUE**

18 53. This Court has jurisdiction over this action. Defendants are engaging in false and
 19 misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance
 20 in Irvine, and the People through their attorneys have the right and authority to prosecute this case
 21 on behalf of the People.

22 54. Venue is proper in this Court because Defendants transact business in California and
 23 San Francisco County, and some of the acts complained of occurred in this venue. Furthermore,
 24 Defendant Distributor McKesson’s principal place of business is in San Francisco County, and
 25 McKesson conducted business and continues to do business throughout the United States and in
 26 the State of California by regularly and continuously distributing prescription opioids throughout
 27 the State of California.
 28

1 **IV. GENERAL FACTUAL ALLEGATIONS**

2 **A. An Overview of the Opioid Epidemic**

3 55. The term “opioid” includes all drugs derived from the opium poppy. The United
4 States Food and Drug Administration describes opioids as follows: “Prescription opioids are
5 powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and
6 morphine, among others, and have both benefits as well as potentially serious risks. These
7 medications can help manage pain when prescribed for the right condition and when used properly.
8 But when misused or abused, opioids can cause serious harm, including addiction, overdose, and
9 death.”⁵

10 56. Prescription opioids with the highest potential for addiction are listed under
11 Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such
12 as codeine and morphine, also known generally as “opiates”), partially synthetic derivatives (such
13 as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

14 57. Historically, opioids were considered too addictive and debilitating for the treatment
15 of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,
16 director of Johns Hopkins University’s Center for Drug Safety and Effectiveness, “[opioids] have
17 very, very high inherent risks . . . and there’s no such thing as a fully safe opioid.”⁶

18 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
19 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
20 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

21 59. Before the 1990s, generally accepted standards of medical practice dictated that
22 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
23 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
24 patients’ ability to overcome pain and function, as well as evidence of **greater** pain complaints as
25

26 ⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

27 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
28 Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

1 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
2 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
3 generally did not prescribe opioids for chronic pain.

4 60. The market for chronic pain patients, however, was much larger, and to take
5 advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for
6 chronic pain.⁷

7 61. As described herein, Defendants engaged in conduct that directly caused doctors to
8 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
9 obligations to prevent diversion of the highly addictive substance.

10 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
11 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
12 for every person in the United States to have a bottle of pills. This represents an increase of 300%
13 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
14 were dispensed per 100 persons.

15 63. Many Americans, including Californians and residents of Irvine, are now addicted
16 to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United States, an
17 increase of more than 22 percent over the previous year. The New York Times reported in
18 September 2017, that the opioid epidemic is now killing babies and toddlers because deadly opioids
19 are "everywhere" and are easily mistaken as candy.⁸ The opioid epidemic has been declared a
20 public health emergency by the President of the United States. The wave of opioid addiction was
21 created by the increase in prescriptions.

22 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
23 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
24 NIH's National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed

25 _____
26 ⁷ See Harriet Ryan et al., *'You want a description of hell?' OxyContin's 12-hour problem*, L.A. Times
(May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20,
2017).

27 ⁸ Julie Turkewitz, *"The Pills are Everywhere:" How the Opioid Crisis Claims Its Youngest Victims*, N.Y.
28 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
(last accessed January 4, 2018).

1 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
2 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
3 80 percent of people who use heroin first misused prescription opioids.

4 65. Drug overdose deaths among all Americans increased more than 200 percent
5 between 1999 and 2015.

6 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
7 there were 4,654 total opioid overdose deaths in 2016.⁹

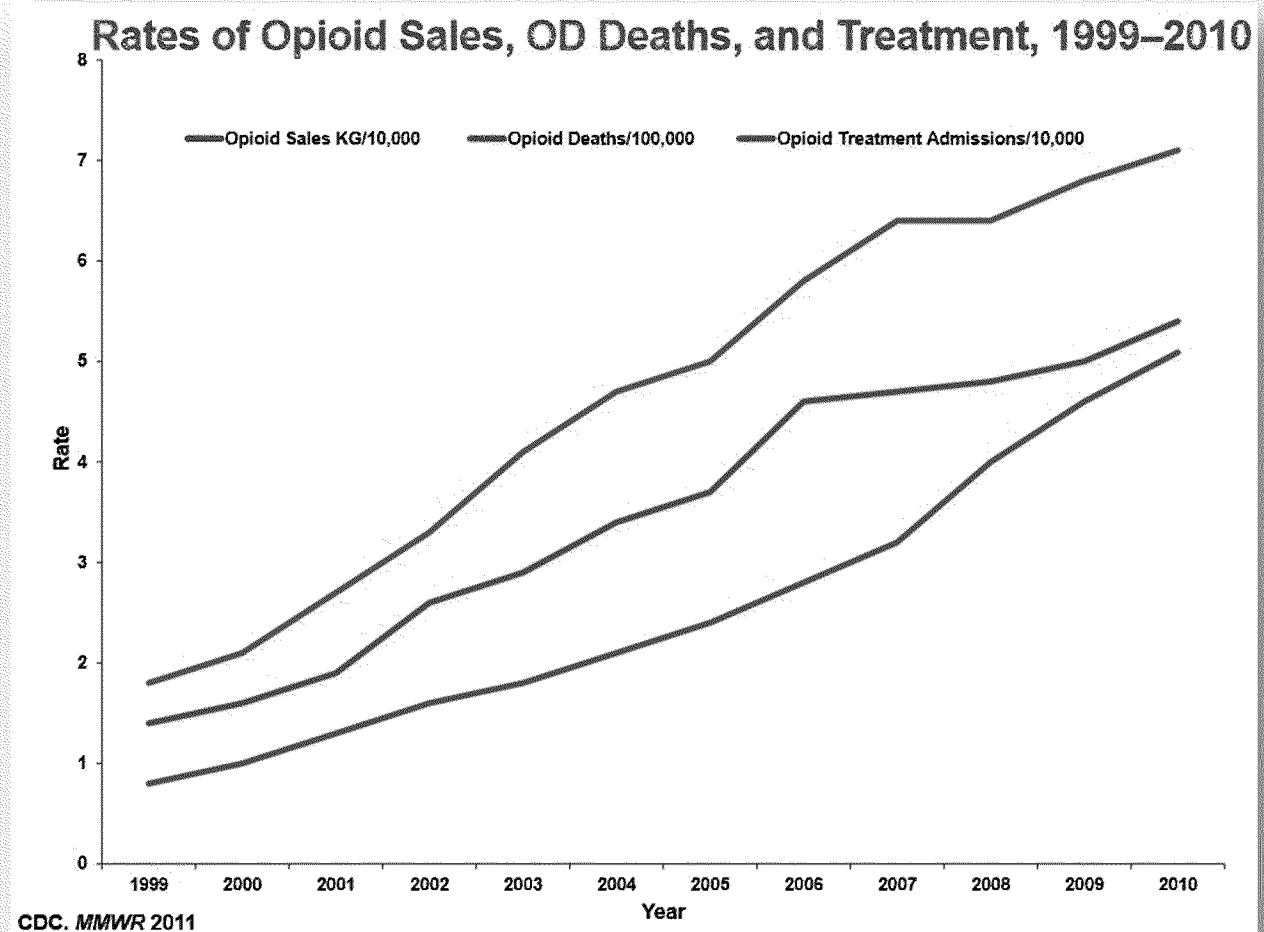
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28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, *California Opioid Summary*, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in Irvine, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants’ messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
2 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
3 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
4 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
5 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
6 carried a low, or no, risk of addiction.

7 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
8 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
9 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
10 of actual addiction began appearing, and advocated that the signs of addiction should be treated
11 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
12 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
13 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
14 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
15 opioid use, including the supposed ability of opioids to improve function and quality of life, even
16 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
17 claims.

18 75. These statements were not only unsupported by or contrary to the scientific
19 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
20 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
21 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

22 76. The Manufacturer Defendants began their marketing schemes decades ago and
23 continue them today.

24 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
25 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
26 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
27
28

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
 24

25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 29, 2017).

27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 100. The Manufacturer Defendants' deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's
6 unbranded advertising stated that "People who take opioids as prescribed usually do not become
7 addicted." This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that "use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use."

10 101. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as "key opinion leaders" or "KOLs"—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants' KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs' professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 104. For example, the New York Attorney General ("NY AG") found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in Irvine and doctors treating residents of Irvine.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 _____
28 ²³ Dr. Portenoy was a member of the board of the APF.

²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 119. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 120. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 121. On information and belief, AAPM is viewed internally by Endo as “industry

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26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 122. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

26
27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in Irvine during the relevant time period, are still available online, and were often
 12 reprinted in the Journal of Pain, which is the official journal of the American Pain Society. The
 13 Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 126. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 128. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 129. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 130. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 131. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
25 marketing materials along with the rights to Kadian, it appears that Actavis
26 continued to use this brochure in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
28 People Living with Pain (2007), which suggests that addiction is rare and
limited to extreme cases of unauthorized dose escalations, obtaining
duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Irvine, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 138. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain *is under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in Irvine, to PartnersAgainstPain.com, which contained false and
14 misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 **Deceptive Claims of Pseudoaddiction**

22 139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
some of its proponents” and reported that despite the fact that Endo trained its sales representative
to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
Management testified to [the NY AG] that he was not aware of any research validating the
‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 141. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including Irvine the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

1 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
 2 widely believed by doctors to detect and deter abuse—“for improving outcomes related to
 3 overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that
 4 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
 5 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
 6 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

7 143. To underplay the risk and impact of addiction and make doctors feel more
 8 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
 9 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
 10 failed to disclose the increased difficulty of stopping opioids after long-term use.

11 144. For example, on information and belief, a 2011 non-credit educational program
 12 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
 13 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

14 145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
 15 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
 16 by gradually decreasing the dose of medication during discontinuation” without mentioning any
 17 hardships that might occur.³⁸ This publication was available on APF’s website until the
 18 organization dissolved in May 2012.

19 146. Detailers for Janssen have told and continue to tell doctors in California, including
 20 Irvine, that their patients would not experience withdrawal if they stopped using opioids.

21 **Deceptive Minimization of Opioid Withdrawal**

22 147. The Manufacturer Defendants also deceptively minimized the significant symptoms
 23 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
 24 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
 25 understated the difficulty of tapering, particularly after long-term opioid use.

26 148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

27
 28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
 December 19, 2017).

recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that “more than a few days of exposure to opioids significantly increases hazards” and “each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk

149. The Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants, are described below:

- a. On information and belief, Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’ acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in Irvine that they should increase the dose of OxyContin, rather than
the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was **no** evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in Irvine, that Opana ER is harder to abuse and given demonstrations to nurse
22 practitioners about Opana ER’s purported abuse deterrent properties.

23
24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
[push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
[ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those statements to be false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

158. Because Orpana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.

159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse, and that its abuse deterrent properties can be defeated.

160. These statements and omissions by Purdue are false and misleading, and conflict with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 27 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 28 430.

⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose
 epidemic*, Business Insider (Mar. 14, 2016), available at [http://www.businessinsider.com/robert-califf-
 abuse-deterrent-drugs-have-a-big-flaw-2016-3](http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3) (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in Irvine, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewharper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

174. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

26 _____
27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by Irvine.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

26
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

28 ⁵² *Id.*

1 misrepresentations deceived and continue to deceive doctors and patients in California, including
2 in Irvine, about the risks and benefits of long-term opioid use. California doctors confirm this.
3 Studies also reveal that many doctors and patients are not aware of or do not understand these risks
4 and benefits. Indeed, patients often report that they were not warned they might become addicted
5 to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid
6 patients found that 4 out of 10 were not told opioids were potentially addictive. Plaintiff is informed
7 and believes that California residents were never told that they might become addicted to opioids
8 when they started taking them, were told that they could easily stop using opioids, or were told that
9 the opioids they were prescribed were less addictive than other opioids.

10 192. Numerous doctors and substance abuse counselors in California note that many of
11 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
12 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
13 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
14 for opioid addiction.

15 193. The Manufacturer Defendants knew and should have known that their
16 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
17 when they made them.

18 194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
19 properties of their opioids caused and continue to cause doctors in California, including doctors in
20 Irvine, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and
21 fibromyalgia, rather than prescribing less addictive medications. Absent Manufacturers
22 Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids
23 to as many patients, and there would not have been as many opioids available for misuse and abuse
24 or as much demand for those opioids.

25 195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
26 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
27 California, including in Irvine. Opioids are the most common means of treatment for chronic pain;
28 20% of office visits now include the prescription of an opioid, and 4 million Americans per year

1 are prescribed a long-acting opioid.

2 196. In California, including Irvine, Manufacturer Defendants' deceptive marketing of
3 the abuse-deterrent properties of their opioids during the past few years has been particularly
4 effective. For example, one survey reports that pain specialists were more likely to recognize that
5 OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those
6 properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using
7 more of it than those who did not know it was an AD opioid. Although sales of AD opioids still
8 represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they
9 represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in
10 opioid sales revenue in 2015).

11 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 198. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 199. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 200. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 201. Diversion can occur at any point in the opioid supply chain.

4 202. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 205. Opioid diversion occurs at an alarming rate in the United States.

23 206. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 **210.** In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 211. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 212. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for Irvine and the people therein.

25 213. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

1 214. Thus, all opioid distributors are required to maintain effective controls against
2 opioid diversion. They are required to create and use a system to identify and report to the California
3 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
4 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
5 and/or orders of unusual frequency. To comply with these requirements, distributors must know
6 their customers, must conduct due diligence, must report suspicious orders, and must terminate
7 orders if there are indications of diversion.

8 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
9 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
10 their obligations under the CSA.

11 216. Under the CSA, anyone authorized to handle controlled substances must track
12 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
13 automated drug reporting system that records and monitors the flow of Schedule II controlled
14 substances from the point of manufacture through distribution to the point of sale. ARCOS
15 accumulates data on distributors' controlled substances and transactions, which are then used to
16 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
17 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
18 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
19 and current record of each substance manufactured, imported, received, sold, delivered, exported,
20 or otherwise disposed of.

21 217. Plaintiff does not bring causes of action based on violations of federal statutes and
22 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
23 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
24 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
25 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
26 prescription opioids.

1. The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Irvine Through Illicit Channels

218. The Distributor Defendants have been and continue to be well-aware of problems posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes that the DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. The distributors are also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor Defendants should look for in order to identify potential diversion.

219. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors, including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. These registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

220. Since 2008, the DEA also has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 Irvine and its residents. Each Distributor Defendant knew or should have known that the opioids
7 reaching Irvine were not being consumed for medical purposes and that the amount of opioids
8 flowing to Irvine was far in excess of what could be consumed for medically necessary purposes.

9 232. The Distributor Defendants negligently or intentionally failed to adequately control
10 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
11 substances would have anticipated the danger of opioid diversion and protected against it by, for
12 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
13 greater oversight, security, and control of supply channels; (c) looking more closely at the
14 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
15 amounts greater than the populations in those areas would warrant; (d) investigating demographic
16 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
17 Irvine; (e) providing information to pharmacies and retailers about opioid diversion; and (f) in
18 general, simply following applicable statutes, regulations, professional standards, and guidance
19 from government agencies and using a little bit of common sense.

20 233. On information and belief, the Distributor Defendants made little to no effort to visit
21 the pharmacies servicing the areas around Irvine to perform due diligence inspections to ensure that
22 the controlled substances the Distributor Defendants had furnished were not being diverted to
23 illegal uses.

24 234. On information and belief, the compensation the Distributor Defendants provided
25 to certain of their employees was affected, in part, by the volume of their sales of opioids to
26 pharmacies and other facilities servicing the areas around Irvine, thus improperly creating
27 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid
28 abuse.

1 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
2 flooding the market in and around Irvine with highly addictive opioids would allow opioids to fall
3 into the hands of children, addicts, criminals, and other unintended users.

4 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
5 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
6 and death. It was also reasonably foreseeable that many of these injuries would be suffered by
7 Irvine residents, and that the costs of these injuries would be borne by Irvine.

8 237. The Distributor Defendants knew or should have known that the opioids being
9 diverted from their supply chains would contribute to the opioid epidemic faced by Irvine, and
10 would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
11 addiction, demand, illegal transactions, economic ruin, and human tragedy.

12 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
13 and around Irvine, but, on information and belief, they nevertheless persisted in a pattern of
14 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
15 with such frequency that they knew or should have known these commonly abused controlled
16 substances were not being prescribed and consumed for legitimate medical purposes.

17 239. The use of opioids by Irvine residents who were addicted or who did not have a
18 medically necessary purpose could not have occurred without the knowing cooperation, assistance,
19 or negligent failure to act of and by the Distributor Defendants. If the Distributor Defendants
20 adhered to effective controls to guard against diversion, Irvine and its residents would have avoided
21 significant injury.

22 240. The Distributor Defendants made substantial profits over the years based on the
23 diversion of opioids into Irvine. The Distributor Defendants knew that Irvine would be unjustly
24 forced to bear the costs of these injuries and damages.

25 241. The Distributor Defendants' intentional distribution of excessive amounts of
26 prescription opioids showed an intentional or reckless disregard for the safety of Irvine and its
27 residents. Their conduct poses a continuing threat to the health, safety, and welfare of Irvine.

28 242. The state laws at issue here are public safety laws.

1 243. The Distributor Defendants' violations constitute prima facie evidence of
2 negligence under state law.

3 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
4 **of Opioids to Irvine Through Illicit Channels**

5 244. The same legal duties to prevent diversion, and to monitor, report, and prevent
6 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
7 were also legally required of the Manufacturer Defendants under California law.

8 245. In addition to a common law duty to exercise reasonable care in the promotion and
9 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
10 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
11 determined by the Board. *See* 16 CCR 1782.

12 246. On information and belief, for over a decade the Manufacturer Defendants have
13 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
14 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
15 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
16 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
17 Manufacturer Defendants breached their duties under state law.

18 247. The Manufacturer Defendants had access to and possession of the information
19 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
20 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
21 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
22 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
23 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
24 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
25 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
26 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer
27 Defendants built receipt of this information into the payment structure for the opioids provided to
28 the opioid distributors.

248. The Manufacturer Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Irvine.

F. The Defendants Knowingly Profit from an Interstate Opioid Crisis

249. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state, city, and county lines in a variety of ways.

250. First, prescriptions written in one state would, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another.

251. When authorities in one state cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of regulatory oversight created a fertile ground for pill mills. Residents of many states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

252. The facts surrounding numerous criminal prosecutions illustrate this common practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught flying to California in attempts to obtain additional sources of supply for their drug operation which consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

253. In another example, a man from Warren County, Ohio, who was sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone

⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

⁵⁹ Andrew Welsh-Huggins, Associated Press, *'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

1 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
2 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
3 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
4 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
5 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

6 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
7 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
8 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
9 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
10 customers were from other states.⁶³

11 255. In yet another case, defendants who operated a pill mill in south Florida within
12 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
13 transported oxycodone back to the area for both use and distribution by local drug trafficking
14 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
15 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
16 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
17 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
18 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
19 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
20

21 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
22 <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
accessed July 25, 2018).

23 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
24 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

25 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
26 accessed July 25, 2018).

27 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
28 [patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

1 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
2 Kentucky residents.”⁶⁵

3 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
4 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
5 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
6 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
7 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
8 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
9 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
10 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
11 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

12 257. While the I-75 corridor was well utilized, prescription tourists also came from other
13 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
14 mills come from as far away as Arizona and Nebraska.⁷⁰

15 258. Similar pipelines developed in other regions of the country. For example, the I-95
16 corridor was another transport route for prescription pills. As the director of the Maine Drug
17 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
18 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
19 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
20 Ohio, and Kentucky.

21 _____
22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s*
24 *Deadliest Drug Epidemic* 171 (2016).

25 ⁶⁷ *Id.* at 172

26 ⁶⁸ *Id.* at 171

27 ⁶⁹ *Id.*

28 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
(last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
(last accessed July 25, 2018)

259. Along the west coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷² Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.

260. Defendants certainly were aware, or should have been aware, that pill mills from around the country were pushing its products. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from data vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The data vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.

261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.

262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,

⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

⁷³ *Id.*

1 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
2 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
3 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

4 ⁷⁴

5 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
6 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
7 sales representative "it was packed with a line out the door, with people who looked like gang
8 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
9 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
10 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
11 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
12 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
13 2010 to inform the authorities.

14 264. Abundant evidence, thus, establishes that prescription opioids migrated between
15 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
16 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
17 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
18 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
19 prescription opioid pills were hard to get in one area, they migrated from another. The
20 manufacturers and distributors were fully aware of this phenomenon and profited from it.

21 265. Defendants each knew or should have known that opioid diversion and abuse was
22 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide
23 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
24 allowed to continue the unlawful diversion of opioids into Irvine.

25 _____
26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages

266. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and the sale of their products, as well as the rates of opioid-related substance abuse, hospitalization, and death among Irvine residents and across the nation. Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of opioids into communities like Irvine, fueling the epidemic.

267. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."⁷⁷

268. Opioids are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

269. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."⁷⁹

270. The increased abuse of prescription opioids—along with growing sales—has contributed to a large number of overdoses and deaths.

271. As shown above, the opioid epidemic has escalated in Irvine with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants' increased distribution of opioids.

272. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to Irvine and areas from which opioids are being diverted to Irvine, has caused the opioid epidemic to include heroin addiction, abuse, and death.

273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Irvine.

⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Irvine.

275. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in Irvine.

276. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in Irvine. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by Irvine and residents of Irvine.

277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Irvine seeks relief, as alleged herein. Irvine also seeks the means to abate the epidemic created by the Defendants.

278. Irvine seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

279. Irvine seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

280. Irvine seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

281. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

282. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

283. The community-based problems require community-based solutions that have been

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed January 8, 2018).

1 limited by budgetary constraints.

2 284. Having profited enormously through the aggressive sale, misleading promotion, and
3 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
4 financial burdens their conduct has inflicted upon Irvine.

5 285. The opioid epidemic still rages because the fines and suspensions imposed by the
6 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
7 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
8 registration numbers and when one facility is suspended, they simply ship from another facility.

9 286. The Defendants have abandoned their duties imposed by the law, taken advantage
10 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
11 Irvine.

12 287. In the course of conduct described in this Complaint, Defendants have acted with
13 oppression, fraud, and malice, both actual and presumed.

14 **H. The Impact of Opioid Abuse on Irvine**

15 288. Defendants' creation, through false and misleading advertising and a failure to
16 prevent diversion, of a virtually limitless opioid market has significantly harmed Irvine and resulted
17 in an abundance of drugs available for non-medical and criminal use and fueled a new wave of
18 addiction and injury. It has been estimated that approximately 60% of the opioids that are abused
19 come, directly or indirectly, through doctors' prescriptions.

20 289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
21 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
22 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
23 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
24 associated with the consumption of a counterfeit version of the prescription drug Norco
25 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has
26 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
27 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
28 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further

1 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
2 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
3 concern.

4 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
5 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
6 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
7 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
8 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

9 291. Even Irvine's youngest residents bear the consequences of the opioid abuse
10 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
11 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
12 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
13 Many Irvine women have become addicted to prescription opioids and have used these drugs during
14 their pregnancies. As a result, many Irvine infants suffer from opioid withdrawal and Neonatal
15 Abstinence Syndrome ("NAS").⁸⁵

16 292. The impact of NAS can be life-long. Most NAS infants are immediately transferred
17 to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require
18 an emergency evacuation for care to save the infant's life. Such emergency transportation can cost
19 thousands of dollars for each occurrence.
20

21 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
22 *year*, LA Times (Oct. 27, 2014), available at <http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html> (last accessed December 21, 2017).

23 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
24 *The Opioid Crisis in Indian Country*, at 37, available at
<https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
25 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US., 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

26 ⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
27 Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
28 21, 2017).

⁸⁵ Jean Y, Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at
<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

293. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

294. Many of the parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

295. Opioid addiction is now the primary reason that Californians seek substance abuse treatment, and admissions to drug treatment facilities in California more than doubled from 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one facility in northern California, up to 90% – started on legal opioid prescriptions.

296. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in California. California faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]” and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each Defendant’s deceptive marketing and distribution scheme are catastrophic and are only getting worse.

297. There is little doubt that each Defendant’s deceptive marketing and distribution scheme has precipitated this public health crisis in California, including Irvine, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

298. The effects of Defendants’ deceptive marketing and distribution scheme has further impacted Plaintiff in a foreseeable way such that Irvine must devote increased resources to the burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For

1 example, tax dollars are required to maintain public safety of places where the addicted homeless
 2 attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight
 3 the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
 4 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
 5 *aureus* (MRSA) are spread by opioid abuse.

6 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
 7 have recruited addicts nationally with false and misleading promises of the medically supervised
 8 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
 9 effective rehabilitation available in beautiful California communities. These for-profit
 10 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
 11 that many have provided substandard care including use of physicians who have had their license
 12 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
 13 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
 14 as long as there are third party payments available, and then throw them out of the facilities to be
 15 homeless. These addicts brought to California by the substandard rehab industry, have further
 16 contributed to the public's burden by discharging addicted homeless into the community who
 17 require further care and rehabilitation at the public's expense, and who commit crimes in California
 18 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
 19 all relevant times when they deceptively marketed their products as non-addictive that such
 20 addiction would be highly difficult to overcome. Defendants knew or should have known that
 21 municipalities, including Irvine, would bear the burden of costs associated with rehabilitation
 22 business of all types.

23 300. The role of Defendants' deceptive marketing and distribution scheme in causing this
 24 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
 25 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
 26 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have
 27 contributed to the severity of the current prescription drug abuse problem." And in August 2016,
 28 the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy

1 marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that opioids
2 are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment
3 specialists, and law enforcement and public health officials confirm that prescription opioids
4 lawfully prescribed by doctors have fueled this epidemic.

5 301. Absent each Defendant’s deceptive marketing scheme and improper distribution,
6 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
7 the opioid epidemic that now exists would have been averted or much less severe.

8 302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
9 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
10 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
11 only engaged in false advertising, they have also created or assisted in the creation of a public
12 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the
13 present is part of its deceptive marketing and distribution scheme and subjects that Defendant to
14 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
15 *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual
16 obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance
17 of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

18 303. Accordingly, Defendants’ conduct, both individually and collectively, has violated
19 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
20 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Irvine does not seek to limit the ability
21 of doctors in California to prescribe opioids. Irvine does not ask this Court to weigh the risks and
22 benefits of long-term opioid use. Instead, Irvine seeks an order requiring Defendants to cease their
23 unlawful promotion and distribution of opioids, to correct their misrepresentations, and to abate the
24 public nuisance they have created. To redress and punish Defendants’ previous and current
25 violations of law that cause and continue to cause harm to Irvine, Plaintiff seeks a judgment
26 requiring Defendants to pay civil penalties, and any fees or costs permitted under law.

27 304. By this action, Irvine further seeks to recoup tax dollars spent already for the
28 consequences of Defendants’ wrongful conduct in causing the opioid epidemic and crisis and its

1 impact on this county and its communities, and to abate the opioid nuisance so Irvine will not be
2 required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
3 wrongful conduct as alleged herein.

4 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
5 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
6 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
7 California spiked by 34% from 2011 to 2013.

8 306. Opioid abuse also contributes to a range of social problems including physical and
9 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
10 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
11 unemployment, and despair. More and more Irvine resources are needed to combat these problems.
12 The prescription opioid crisis also diminishes Irvine's available workforce, decreases productivity,
13 increases poverty, and requires greater governmental expenditures by Irvine.

14 307. The prescription opioid crisis has directly financially injured Irvine. The crisis has
15 led to an increased demand for, *inter alia*, security services (such as police, EMS, detention), child
16 protective services, health services, clean-up services, and legal services. Irvine has also had to hire
17 additional staff and expend additional resources to manage the demand.

18 308. Irvine's medical services have seen an increase in opioid-related health problems
19 among Irvine residents, including, but not limited to, infants born with opioid-related medical
20 conditions. This has resulted in increased demand and increased expenses.

21 309. Irvine has also suffered substantial financial damages in the form of lost productivity
22 of Irvine employees and residents, lost economic activity, lost reputation and good will, and the
23 lost opportunity for growth. These damages have been suffered and continue to be suffered directly
24 by Irvine.

25 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
26 their homes and their families. Some will get treatment and fewer will successfully complete it;
27 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
28 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from

1 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
2 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
3 drug transactions; or dying from opioid-induced heart or neurological disease.

4 311. Irvine also has suffered substantial financial damages in the form of lost taxes paid
5 by its residents and businesses as a result of lost earnings and productivity.

6 312. While the use of opioids has taken an enormous toll on Irvine and its residents,
7 Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in
8 revenue for drug companies like the Defendants. Indeed, on information and belief, each Defendant
9 experienced a material increase in sales, revenue, and profits from the unlawful conduct described
10 above.

11 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
12 **Asserting Statutes of Limitations As Defenses**

13 313. Defendants' conduct has continued from the early 1990s through today and remains
14 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
15 continuous injury. The damages have not occurred all at once but have continued to occur and have
16 increased as time progresses. The tort is not completed nor have all the damages been incurred until
17 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
18 public nuisance remains unabated.

19 314. Defendants are equitably estopped from relying upon a statute of limitations defense
20 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
21 assure the public that they were undertaking efforts to comply with their obligations under the
22 controlled substances laws, all with the goal of continuing to generate profits.

23 315. For example, a Cardinal Health executive claimed that it uses "advanced analytics"
24 to monitor its supply chain, and assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."⁸⁶

26
27 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No*
28 *One Was Doing Their Job,"* Wash. Post (Oct. 22, 2016), available at
[https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-61526111.2)
[of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-61526111.2)

1 316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
2 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
3 curbing the opioid epidemic in our country.”⁸⁷

4 317. Defendants, through their trade associations, filed an amicus brief that represented
5 that Defendants took their duties seriously, complied with their statutory and regulatory
6 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

7 318. Defendants purposely concealed their wrongful conduct, including by assuring the
8 public and governmental authorities that they were complying with their obligations and were
9 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
10 behavior by providing the public with false information about opioids and have continued to use
11 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
12 is continuing to this day.

13 319. Defendants have also concealed and prevented discovery of information, including
14 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
15 and illegal activities.

16 320. Defendants also lobbied Congress and actively attempted to halt DEA investigations
17 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
18 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a
19 distributor’s license was raised.

20 321. In addition, the Defendants fraudulently attempted to convince the public that they
21 were complying with their legal obligations and working to curb the opioid epidemic.

22 322. Because the Defendants concealed the facts surrounding the opioid epidemic, Irvine

23 _____
24 7b6c1998b7a0_story.html (last accessed December 21, 2017)

25 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
26 *Opioid Abuse*, Wash. Post, (Dec. 22, 2016), available at
https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed December 21,
2017).

27 ⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
28 Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

⁸⁹ See Higham and Bernstein, *supra* note 53.

1 did not know if the existence or scope of the Defendants' misconduct, and could not have acquired
2 such knowledge earlier through the exercise of reasonable diligence.

3 323. Defendants intended that their false statements and omissions be relied upon,
4 including by Irvine, and its residents.

5 324. Defendants knew of their wrongful acts and had material information pertinent to
6 their discovery, but concealed that information from the public, including Irvine, and its residents.
7 Only Defendants knew of their widespread misinformation campaign and of their repeated,
8 intentional failures to prevent opioid diversion.

9 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
10 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
11 opioid crisis have only recently come to light.

12 326. Defendants had actual knowledge that their conduct was deceptive, and they
13 intended it to be deceptive.

14 327. Irvine was unable to obtain vital information regarding these claims absent any fault
15 or lack of diligence on Irvine's part.

16 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

17 **A. The Marketing Scheme**

18 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
19 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
20 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
21 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
22 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
23 long-term, chronic pain. Through their personal relationships, the members of this marketing
24 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
25 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
26 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

27 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
28 risks and dangers of opioids from the medical community and the public, including Plaintiff, and

1 made misleading statements and misrepresentations about opioids that downplayed the risk of
2 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
3 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
4 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
5 of an invented condition the Manufacturer Defendants named “pseudoaddiction”; (d) withdrawal
6 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
7 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
8 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
9 formulations provide a solution to opioid abuse.

10 330. The marketing scheme devised, implemented and conducted by the Manufacturer
11 Defendants was designed to ensure that they unlawfully increased their sales and profits through
12 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
13 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
14 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
15 network as described above.

16 331. There was regular communication between the Manufacturer Defendants, Front
17 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
18 exchanged. Typically, the coordination, communication and payment occurred, and continues to
19 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
20 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
21 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
22 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
23 each agreed and took actions to hide the scheme and continue its existence.

24 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants’
25 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
26 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
27 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
28 Manufacturer Defendants, Front Groups and KOLs’ unlawful fraud, the Front Groups would have

1 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
2 their members and constituents. By failing to disclose this information, Front Groups perpetuated
3 the marketing scheme, and reaped substantial benefits.

4 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
5 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
6 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
7 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
8 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
9 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
10 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
11 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
12 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
13 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
14 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
15 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

16 334. As public scrutiny and media coverage focused on how opioids ravaged
17 communities in California and throughout the United States, the Front Groups and KOLS did not
18 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
19 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
20 using opioids for chronic pain.

21 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
22 categories of activities in furtherance of the marketing scheme. As described herein, the
23 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
24 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
25 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
26 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
27 and (d) efforts to limit prescriber accountability.

28 336. In addition to disseminating misrepresentations about the risks and benefits of

1 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
2 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
3 criticized or undermined the CDC Guidelines which represented “an important step – and perhaps
4 the first major step from the federal government - toward limiting opioid prescriptions for chronic
5 pain.”

6 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
7 the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not
8 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
9 of the individuals who participated in the construction of these guidelines.”

10 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
11 president, stating “that the CDC guideline makes disproportionately strong recommendations based
12 upon a narrowly selected portion of the available clinical evidence.”

13 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
14 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
15 “neutral” and more “scientific” than the Manufacturer Defendants themselves. Without the work
16 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
17 scheme could not have achieved its common purpose.

18 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to
19 be prescribed and used for chronic pain throughout Irvine, and the epidemic continues to injure
20 Plaintiff, and consume the resources of Plaintiff’s emergency health services and law enforcement
21 systems.

22 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
23 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
24 in the object of the scheme, and functioned within a structure designed to effectuate the scheme’s
25 purpose.

26 **B. The Distribution Scheme**

27 342. Faced with the reality that they will now be held accountable for the consequences
28 of the opioid epidemic they created, members of the industry resort to “a categorical denial of any

1 criminal behavior or intent.”⁹⁰ Defendants’ actions went far beyond what could be considered
 2 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
 3 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
 4 competitive, with the common purpose and achievement of vastly increasing their respective profits
 5 and revenues by exponentially expanding a market that the law intended to restrict.

6 343. Knowing that dangerous drugs have a limited place in our society, and that their
 7 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
 8 and addiction causes to individuals, society and governments, California enacted California
 9 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
 10 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
 11 to detect and report such activity.

12 344. If morality and the law did not suffice, competition dictates that the Distributor
 13 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
 14 if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior
 15 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
 16 dictates that it would do so.

17 345. The Distributor Defendants’ scheme required the participation of all. If any one
 18 member broke rank, its compliance activities would highlight deficiencies of the others, and the
 19 artificially high quotas they maintained through their scheme would crumble. But, if all the
 20 members of the enterprise conducted themselves in the same manner, it would be difficult for state
 21 authorities or the DEA to go after any one of them. Accordingly, through the connections they
 22 made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the
 23 Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly,
 24 in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting
 25 Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the
 26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
 28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the Distributor Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

346. As described above, at all relevant times, the Distributor Defendants conspired together for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

347. At all relevant times, as described above, the Distributor Defendants exerted control over, conducted and/or participated in distribution scheme by fraudulently claiming that they were complying with their duties under California law to report suspicious orders and to maintain systems to detect and report such activity.

348. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators' ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the "Ensuring Patient Access and Effective Drug Enforcement Act."⁹¹

⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21,

349. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

350. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

351. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

352. Each Defendant's conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under California Business & Professions Code § 17536.

353. As a members of the boards of various Purdue entities, the Sacklers oversaw all aspects of Purdue's marketing and promotion of opioid products. As board members who were personally active in directing Purdue's operations, the Sackler Defendants knew, or should have known, of Purdue's deceptive marketing tactics of opioid products.

2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 354. The Sackler Defendants also were aware of specific examples of deceptive
2 marketing through receipt of call note reviews in their capacities as board members. On information
3 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
4 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
5 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

6 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
7 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
8 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
9 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

10 356. By 2006, prosecutors at the United States Department of Justice found damning
11 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
12 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
13 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
14 events and side effects than other pain medications.

15 357. As members of the family that owns Purdue, the Sackler Defendants personally
16 benefitted from the success of OxyContin. At various points, as directors, they approved the
17 distribution of funds from Purdue to shareholders, including themselves and their extended family.

18 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
19 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
20 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
21 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
22 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
23 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
24 the opioid related liabilities of the companies from which they were transferred.

25 359. Plaintiff is informed and believes that due to the billions of dollars in profits that
26 have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to
27 satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced
28 litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the

1 Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly
2 profited and received the benefits of that wrongdoing.

3 **VII. CAUSES OF ACTION**

4 **FIRST CAUSE OF ACTION**

5 **(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)**

6 360. Plaintiff realleges and incorporates herein by reference each and every allegation in
7 paragraphs 1 through 359 above as if set forth fully herein.

8 361. California Civil Code § 3479 provides that “anything which is injurious to health ...
9 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
10 interfere with the comfortable enjoyment of life or property ... is a nuisance.”

11 362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at
12 the same time an entire community or neighborhood, or any considerable number of persons,
13 although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

14 363. California Civil Code § 3490 states that “no lapse of time can legalize a public
15 nuisance, amounting to an actual obstruction of public right.”

16 364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought
17 by Irvine to abate the public nuisance created by the Defendants.

18 365. Each Defendant, acting individually and in concert, has created or assisted in the
19 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment
20 of life and property of entire communities or neighborhoods or of any considerable number of
21 persons in Irvine in violation of California Civil Code §§ 3479 and 3480.

22 366. The public nuisance is substantial and unreasonable. Defendants’ actions caused and
23 continue to cause the public health epidemic described above in Irvine, and that harm outweighs
24 any offsetting benefit.

25 367. Defendants knew and should have known that their promotion and distribution of
26 opioids was false and misleading and that their deceptive marketing scheme would create or assist
27 in the creation of the public nuisance—i.e., the opioid epidemic.

28 368. Defendants’ actions were, at the very least, a substantial factor in opioids becoming

1 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
 2 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
 3 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
 4 so widespread, and the opioid epidemic that now exists would have been averted or much less
 5 severe.

6 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
 7 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
 8 can be abated.

9 370. Each Defendant is liable for public nuisance because its conduct at issue is
 10 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
 11 endangers the safety, health, morals, comfort, or repose of a considerable number of people in
 12 Irvine. Defendants' conduct is also indecent or offensive to the senses, and constitutes an
 13 obstruction to the free use of property sufficient to constitute an interference with the people of
 14 Irvine's comfortable enjoyment of life or property.

15 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
 16 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
 17 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
 18 unreasonable interference with Irvine and its residents' public rights, including, but not limited to,
 19 the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free from
 20 disturbance and reasonable apprehension of danger to person or property.

21 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
 22 interfered with Irvine and its residents' public rights by, *inter alia*, engaging in a promotion and
 23 marketing scheme that pushed the use of opioids for indications not federally approved, and by
 24 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
 25 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
 26 Defendants failed to comply with federal law.

27 373. Defendants have also unlawfully and intentionally distributed opioids or caused
 28 opioids to be distributed within and without Irvine absent effective controls against diversion. Such

1 conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain
2 effective controls against diversion include Defendants' failure to effectively monitor for
3 suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

4 374. Defendant's unreasonable interference with Irvine residents' public rights include,
5 but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
6 expenditures to combat and address these harms. These damages have been suffered and continue
7 to be suffered directly by Irvine and its residents.

8 375. Defendants' actions have also created a palpable climate of fear, distress,
9 dysfunction and chaos among residents of Irvine where opioid diversion, abuse, and addiction are
10 prevalent and where diverted opioids are used frequently. Specifically, Defendants conduct has
11 caused, among other things, (a) routine separation of children from their parents who have fallen
12 victim to easy access to opioids and/or related crime; (b) children to have easy access and to become
13 addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for
14 loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces
15 and property; (e) property crimes throughout Irvine; (f) employers to lose the value of productive
16 and healthy employees; (g) increased public health and safety costs; (h) a reduction in potential
17 property values within Irvine; and (i) a decrease in tax revenues for Irvine.

18 376. The impact of Defendants' conduct on Irvine is of a continuing nature. Defendants'
19 conduct will undoubtedly continue to cause long-lasting effects on their public rights.

20 377. Defendants knew or should have known that their actions would lead to the national
21 opioid epidemic and to the resulting injuries to the public rights of Irvine.

22 378. Irvine has sustained a special and peculiar injury because its damages include, *inter*
23 *alia*, health service expenditures, public safety expenditures, payment of opioid addiction
24 treatment, decreased tax revenues, a reduction in potential property values, and other costs related
25 to opioid addiction treatment and overdose prevention.

26 379. The externalized risks associated with Defendants' nuisance-creating conduct as
27 described herein greatly exceed the internalized benefits.

28 380. Defendants' actions are a direct and proximate contributing cause of the opioid

1 epidemic and the injuries to the public rights of Irvine and its residents.

2 381. Defendants, individually and collectively, are at the very least, a substantial factor
3 in causing the national opioid epidemic and of the injuries to Irvine and its residents.

4 382. The injuries to the public rights of Irvine and its residents are indivisible injuries.

5 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
6 if unabated, will continue to cause an unreasonable interference with public rights of Irvine and its
7 residents.

8 384. Defendants' conduct is ongoing and persistent, and Irvine seeks all damages flowing
9 from Defendants' conduct. Irvine seeks economic losses (direct, incidental, and/or consequential
10 pecuniary losses) resulting from Defendants' illegal and wrongful conduct described above. Irvine
11 does not seek damages for the wrongful death, physical personal injury, or emotional distress
12 caused by Defendants' actions.

13 385. Pursuant to Code of Civil Procedure § 731, Irvine requests an order providing for
14 abatement of the public nuisance that Defendants created or assisted in the creation of, and
15 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

16 **SECOND CAUSE OF ACTION**
17 **(Fraud – Against All Defendants)**

18 386. Plaintiff realleges and incorporates herein by reference each and every allegation in
19 paragraphs 1 through 385 above as if set forth fully herein.

20 387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set
21 forth herein

22 388. The Defendants made fraudulent misrepresentations and omissions of material fact.
23 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
24 were intended to induce reliance.

25 389. Those misrepresentations and omissions were known to be untrue by the
26 Defendants, or were recklessly made.

27 390. As alleged herein, the Manufacturer Defendants engaged in false representations
28 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the

1 dangers of abuse, and the risks of addiction.

2 391. As alleged herein, Defendants made false statements and/or omissions regarding
3 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
4 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
5 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
6 opioids, within Irvine.

7 392. Defendants made those misrepresentations and omissions in an intentional effort to
8 deceive Irvine and its residents, despite the Defendants' knowledge of the dangers of such use of
9 prescription opioids.

10 393. In addition and independently, Defendants had a duty not to deceive Plaintiff
11 because Defendants had in their possession unique material knowledge that was unknown, and not
12 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

13 394. The Defendants continued making those misrepresentations, and failed to correct
14 those material omissions, despite repeated regulatory settlements and publications demonstrating
15 the false and misleading nature of the Defendants' omissions and/or claims.

16 395. While Defendants had a duty to disclose the above-referenced material facts, they
17 nevertheless concealed them. These false representations and concealed facts were material to the
18 conduct and actions at issue. Defendants made these false representations and concealed facts with
19 knowledge of the falsity of their representations and did so with the intent of misleading Irvine, its
20 residents, the public, and persons on whom these entities relied.

21 396. Defendants intended and had reason to expect under the operative circumstances
22 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
23 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
24 and that these entities would act or fail to act in reasonable reliance thereon.

25 397. Irvine, its residents, and others, did in fact rightfully, reasonably, and justifiably rely
26 on Defendants' representations and/or concealments, both directly and indirectly.

27 398. For instance, doctors, including those serving Irvine and its residents, relied on the
28 Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.

1 Patients, including residents of Irvine, relied on the Defendants' misrepresentations and omissions
2 in taking prescription opioids for chronic pain relief.

3 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
4 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
5 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
6 effective response to the opioid crisis.

7 400. Defendants' misconduct alleged in this case is ongoing and persistent.

8 401. Irvine has experienced an unprecedented opioid addiction and overdose epidemic
9 leading to increased costs for, *inter alia*, emergency services, treatment services, security services,
10 and lost productivity to Irvine's workforce.

11 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
12 result of Defendants' fraudulent conduct.

13 403. As a direct and foreseeable consequence of Defendants' fraud, Irvine has incurred
14 and continues to incur damages in an amount to be proved at trial consisting of costs for opioid
15 addiction treatment and its secondary consequences in excess of those Irvine would have otherwise
16 incurred.

17 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
18 fraudulent, entitling Irvine to punitive damages.

19 **THIRD CAUSE OF ACTION**
20 **(Negligence – Against All Defendants)**

21 405. Plaintiff realleges and incorporates herein by reference each and every allegation in
22 paragraphs 1 through 404 above as if set forth fully herein.

23 406. To establish actionable negligence in California, Plaintiff must show a duty, a breach
24 of that duty, and injury resulting proximately therefrom.

25 407. Defendants have a duty to exercise reasonable care under the circumstances, in light
26 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
27 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
28 and still have, a duty to exercise reasonable care to prevent the threatened harm.

1 408. In addition, Defendants had a duty not to breach the standard of care established
2 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
3 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
4 to abuse, and to develop and maintain systems to detect and report such activity.

5 409. Defendants voluntarily undertook a legal duty to prevent the diversion of
6 prescription opioids by engaging in the distribution of prescription opioids and by making public
7 promises to prevent the diversion of prescription opioids.

8 410. Defendants knew of the serious problem posed by prescription opioid diversion and
9 were under a legal obligation to take reasonable steps to prevent diversion.

10 411. Defendants knew of the highly addictive nature of prescription opioids and of the
11 high likelihood of foreseeable harm to patients and communities, including Irvine, from
12 prescription opioid diversion.

13 412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
14 in accordance with applicable standards of conduct in advertising, marketing, selling, and
15 distributing opioid products in a safe manner to minimize the risk of addiction in patients and
16 resultant harm to those patients, their families and their communities, and to taxpayers and
17 municipal government such as Irvine which must incur enormous expenditures for prevention,
18 treatment, emergency response and law enforcement costs and other foreseeable costs related to the
19 need to address the consequences of a large number of residents that become addicted to opioids as
20 a result of Defendants' conduct.

21 413. As described throughout the Complaint, Defendants breached their duties to
22 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
23 monitor for, failing to report, and filling highly suspicious orders time and again.

24 414. As described throughout the Complaint, in language expressly incorporated herein,
25 Defendants misrepresented their compliance with their duties under the law and concealed their
26 noncompliance and shipments of suspicious orders of opioids to Irvine and destinations from which
27 they knew opioids were likely to be diverted into Irvine, in addition to other misrepresentations
28 alleged and incorporated herein.

1 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
2 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
3 purported benefits of long-term use of opioids for the treatment of chronic pain.

4 416. Manufacturer Defendants knew or should have known, that their affirmative
5 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
6 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
7 representatives, and internal documents, should have put them on notice that such harm was not
8 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
9 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
10 and the public.

11 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
12 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

13 418. Defendants' misconduct alleged in this case is ongoing and persistent.

14 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
15 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
16 great probability of causing substantial harm.

17 420. As is described throughout this Complaint, Defendants acted without even slight
18 diligence or scant care, and with indifference, and were negligent in a very high degree,
19 disregarding the rights and safety of other persons, and said actions have a great probability of
20 causing substantial harm.

21 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
22 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
23 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
24 minimize the risk of addiction in patients and resultant harm to those patients, their families and
25 their communities, and to taxpayers and municipal government such as Irvine, including, but not
26 limited to, the following:

- a. Foreseeability of harm to Irvine: Defendants were aware or reasonably should have been aware of the risk of addiction of a large number of patients in places such as Irvine, and need for their care and treatment and in handling other consequences of their addiction and that such costs would be borne by local governments such as Irvine;
- b. Degree of certainty Irvine suffered harm: Irvine has suffered enormous harm and costs in addressing treatment of addicted patients, including but not limited to expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences of a large number of residents that become addicted to opioids as a result of Defendants' conduct;
- c. Closeness of connection between Irvine's harm: The explosion of opioid addiction and the presence of opioid addicted patients in Irvine as a result of Defendants' conduct has resulted in expenditures directly for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences;
- d. Moral blame attached to Defendants' conduct: Defendants' knew or should have known that their wrongful conduct, actions and omissions would result in an explosion of patients who would become addicted to opioids, and that a vast opioid epidemic would result from the prescription of opioids to tens of millions of patients nationwide, including within Irvine, and that the costs would be borne by the state, county and municipal local governments, while Defendants profited tens of billions of dollars collectively from the widespread use of prescription opioid products;

- e. Policy of preventing future harm: As a direct and foreseeable result of Defendants' wrongful conduct, the opioid epidemic and crisis has and continues to occur on a vast scale both nationally and locally in places such as Irvine resulting in tremendous harm and cost to the patients, their families and the communities in dealing with this epidemic and crisis, and there is a need to ensure that the costs of such wrongful conduct is borne by Defendants so that parties contemplating such or similar conduct in the future know they will be held responsible for such harm;
- f. Extent of burden to Defendants: There is no burden to Defendants in that state and other law precludes them from engaging in the conduct alleged herein, and there is no burden from precluding Defendants from profiting from their wrongful conduct and operating within the confines of the law in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and municipal government such as Plaintiff Irvine; and
- g. Consequences to the community of imposing a duty to exercise care with resulting liability for breach: Imposing a duty to not engage in Defendants' wrongful conduct of advertising, marketing, selling and distributing opioid products in an unsafe manner would minimize the risk of addiction in patients, and liability for a breach of this duty would benefit communities such as Irvine in that they would not have to incur the foreseeable costs of the opioid epidemic gripping the country and the nation.

422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled

1 substances laws cited above.

2 423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
3 and will continue to suffer economic damages including, but not limited to, significant expenses
4 for security services, emergency, health, prosecution, corrections, and rehabilitation services, as
5 well as the cost of opioid addiction treatment paid by Irvine.

6 424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
7 and will continue to suffer stigma damage, non-physical property damage, and damage to its
8 proprietary interests.

9 425. Defendants' breaches of their duty of care foreseeably and proximately caused
10 damage to Irvine and its residents.

11 426. Manufacturer Defendants are guilty of negligence per se in that the Defendants
12 violated applicable California laws, statutes, and regulations, in the manner in which they
13 advertised, marketed, sold and distributed opioid products.

14 427. Distributor Defendants are guilty of negligence per se in that the Defendants violated
15 California laws, statutes, and regulations designed to protect Plaintiff from the harms it has
16 suffered, including, but not limited to, the following:

- 17 a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug,
18 and Cosmetic Laws, California Health & Safety Code § 110390;
- 19 b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that
20 had been falsely advertised in violation of the Sherman Food, Drug, and
21 Cosmetic Laws, California Health & Safety Code § 110395;
- 22 c. Defendants received in commerce opioids that were falsely advertised or
23 delivered or proffered for delivery opioids that were falsely advertised in
24 violation of the Sherman Food, Drug, and Cosmetic Laws, California Health &
25 Safety Code § 110400;

- d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;
- e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and
- f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Irvine. Irvine, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Irvine to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

430. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

431. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within Irvine, including from opioids foreseeably and deliberately diverted within and into Irvine.

432. Plaintiff has expended substantial amounts of money in an effort to remedy or

1 mitigate the societal harms caused by Defendants' conduct.

2 433. These expenditures include, but are not limited to, the provision of emergency
3 medical services and treatment services to people who use opioids.

4 434. These expenditures have helped sustain Defendants' businesses.

5 435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
6 externalities: the cost of the harms caused by Defendants' improper distribution practices.

7 436. Defendants were aware of these obvious benefits, and their retention of the benefit
8 is unjust.

9 437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
10 benefited from those payments because they allowed them to continue providing customers with a
11 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
12 Defendants obtained enrichment they would not otherwise have obtained. Because of their
13 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
14 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
15 lacks a remedy provided by law.

16 438. Defendants' misconduct alleged in this case is ongoing and persistent.

17 439. Defendants have unjustly retained benefits to the detriment of Irvine, and
18 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
19 good conscience.

20 440. Irvine is entitled to restitution and disgorgement from Defendants in an amount to
21 be determined at trial.

22 **FIFTH CAUSE OF ACTION**
23 **(Civil Conspiracy – Against All Defendants)**

24 441. Plaintiff realleges and incorporates herein by reference each and every allegation in
25 paragraphs 1 through 440 above as if set forth fully herein.

26 442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
27 and/or distribution of opioids into California and Irvine.

28 443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in

1 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
2 and Irvine.

3 444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
4 report, and prevent suspicious orders of opioids.

5 445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
6 conspiracy by increasing the volume of opioid sales in the United States through creating a market
7 for non-medical use of opioids of epidemic proportions.

8 446. Many of the Manufacturing Defendants are members, participants, and/or sponsors
9 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
10 the HDA to give further assistance to the conspiracy.

11 447. The Manufacturing Defendants hid from the general public and suppressed and/or
12 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
13 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
14 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

15 448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
16 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
17 to commit acts of fraud.

18 449. Indeed, for the Supply Chain Defendants’ fraudulent scheme to work, each of the
19 Supply Chain Defendants had to agree to implement similar tactics.

20 450. By intentionally refusing to report and halt suspicious orders of their prescription
21 opioids, Supply Chain Defendants engaged in a fraudulent scheme.

22 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
23 conspiracy, the Supply Chain Defendants engaged in a scheme of deception by refusing to identify
24 or report suspicious orders of prescription opioids that they knew were highly addictive, subject to
25 abuse, and were actually being diverted into the market of non-medical use.

26 452. Defendants further unlawfully marketed opioids in California and Irvine in
27 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
28 dissemination of false and misleading information about the safety and efficacy of long-term opioid

1 use through, among other things: (a) the use of “Front Groups” that appeared to be independent of
2 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
3 continuing medical education (“CME”) programs controlled and/or funded by the Defendants; (d)
4 hiring and deploying so-called “key opinion leaders” or “KOLs” who were paid by the Defendants
5 to promote their message; and (e) the “detailing” activities of the Defendants’ sales forces, which
6 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
7 physicians lacking the expertise of pain care specialists.

8 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
9 unbiased, independent patient-advocacy and professional organizations in order to disseminate
10 patient education materials, a body of biased and unsupported scientific “literature,” and “treatment
11 guidelines” that promoted the Defendants’ false messages.

12 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
13 influence prescribers’ habits by promoting the Defendants’ false message through, among other
14 things, writing favorable journal articles and delivering supportive CMEs as if they were
15 independent medical professionals, thereby further obscuring the Defendants’ role in the
16 conspiracy.

17 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
18 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
19 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
20 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
21 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
22 were industry-friendly and would work together with the Defendants to advance the conspiracy.

23 456. Defendants’ conspiracy and acts in furtherance thereof are alleged in detail in this
24 Complaint, including, without limitation, in Plaintiff’s Counts for violations California Statutes.
25 Such allegations are specifically incorporated herein.

26 457. Defendants acted with a common understanding or design to commit unlawful acts,
27 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
28 proximately caused the injuries alleged herein.

458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

459. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution practices of their competitors to the authorities, which they had a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

461. Defendants' misconduct alleged in this case is ongoing and persistent.

462. As a result of Defendants' conspiracy, Irvine is entitled to compensatory damages in an amount to be proved at trial.

463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and fraudulent, entitling Irvine to punitive damages.

SIXTH CAUSE OF ACTION

(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)

464. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 463 above as if set forth fully herein.

465. California Business & Professions Code § 17500 makes it unlawful for a business to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning ... real or personal property ... which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.”

466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign designed to disseminate false or misleading statements designed to promote the belief that opioid drugs could safely be used in a non-addictive manner.

1 467. By way of example, Actavis's predecessor created a patient brochure for Kadian in
2 2007 that deceptively stated that needing to up one's dose to achieve the same treatment outcome
3 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

4 468. Actavis's predecessor caused a patient education brochure, Managing Chronic Back
5 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
6 claimed that it is "less likely if you have never had an addiction problem."

7 469. Cephalon and Purdue sponsored research and publications that falsely and
8 deceptively stated opioids did not have "ceiling dose."

9 470. Purdue created websites, available to the public that instructed patients to seek new
10 medical providers out if their current provider would not increase their dose.

11 471. Defendants' false and deceptive advertising practices resulted in increased opioid
12 dosages being prescribed to Irvine's residents, increasing the incidence of opioid addiction and
13 overdose in Irvine.

14 472. Distributor Defendants also repeatedly omitted material information and/or falsely
15 represented that they were effectively preventing diversion and were monitoring, reporting, and
16 preventing suspicious orders.

17 473. As alleged above, Defendants' statements about the risks associated with opioid use
18 were not supported by or were contrary to the scientific evidence.

19 474. As alleged above, each Defendant's conduct, separately and collectively, was likely
20 to deceive California payors who purchased or covered the purchase of opioids.

21 475. Irvine seeks restitution and injunctive relief under California Business &
22 Professions Code § 17535.

23 476. Irvine also seeks an order assessing a civil penalty of two thousand five hundred
24 dollars (\$2,500) against Defendants for each violation of California's False Advertising Law
25 pursuant to California Business & Professions Code § 17536.

26 **SEVENTH CAUSE OF ACTION**
27 **(Negligent Failure to Warn— Against Manufacturer Defendants)**

28 477. Plaintiff realleges and incorporates herein by reference each and every allegation in

1 paragraphs 1 through 476 above as if set forth fully herein.

2 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
3 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
4 adequately warning the medical profession about the risk of addiction from the use of opioid
5 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
6 cancel out, and render meaningless any written warnings given about the risk of addiction from the
7 use of opioid products.

8 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
9 to adequately warn the medical profession about the risk of addiction from the use of opioid
10 products, including by overpromoting and over-marketing opioid products in a manner so as to
11 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
12 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
13 products in situations and for patients who should not have been using those drugs or should have
14 used them only as a last resort before other means were used or other less addictive and dangerous
15 drugs were prescribed.

16 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
17 and overpromoting and over-marketing the use of prescription opioid products, there is now a
18 national opioid addiction epidemic, including in Irvine. The People, as a further direct and
19 proximate consequence and result thereof, sustained injuries and damages including but not limited
20 to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs,
21 law and regulatory enforcement costs, opioid disposal programs, and measures for prevention of
22 further opioid abuse and addiction.

23 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
24 fraudulent, entitling Irvine to punitive damages.

25 **EIGHTH CAUSE OF ACTION**
26 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler Defendants)**

27 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
28 paragraphs 1 through 481 above as if set forth fully herein.

1 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
2 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
3 possess a right to payment from Purdue.

4 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
5 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
6 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
7 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

8 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
9 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
10 including Plaintiff.

11 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
12 them pursuant to California Civil Code § 3439.04(a)(1).

13 **NINTH CAUSE OF ACTION**
14 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

15 487. Plaintiff realleges and incorporates herein by reference each and every allegation in
16 paragraphs 1 through 486 above as if set forth fully herein.

17 488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
18 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
19 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
20 of its judgment against Purdue entered in this action.

21 489. After the Sackler Defendants became aware in or about 1999 that Purdue faced
22 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
23 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping
24 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
25 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
26 Defendants and their extended family.

27 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
28 objective of their fraudulent scheme and participated in a coordinated, common course of conduct

1 to commit acts of fraud.

2 491. Purdue and the Sackler Defendants acted with a common understanding or design
3 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
4 excuse, which directly and proximately caused the injuries alleged herein.

5 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
6 unlawfully, and without a reasonable or lawful excuse.

7 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
8 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
9 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
10 judgment entered in this action.

11 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
12 compensatory damages in an amount to be proved at trial.

13 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
14 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

15 **PRAYER FOR RELIEF**

16 WHEREFORE, Irvine and the People respectfully request judgment in their favor
17 granting the following relief:
18

- 19 a) Entering Judgment in favor of Irvine and the People in a final order against each of
20 the Defendants;
- 21 b) An award of actual and consequential damages in an amount to be determined at
22 trial;
- 23 c) An order obligating Defendants to disgorge all revenues and profits derived from
24 their scheme;
- 25 d) An order declaring that Defendants have made, disseminated as part of a plan or
26 scheme, or aided and abetted the dissemination of false and misleading statements
27 in violation of the False Advertising Law;
- 28 e) Enjoin Defendants from performing or proposing to perform any further false or
misleading statements in violation of the False Advertising Law. Any injunctive
relief Plaintiff obtain against Purdue in this action shall not be duplicative of any
injunctive terms that remain in place from the Final Judgment;

- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff’s judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;
- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;
- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff’s costs, including reasonable attorneys’ fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and

1 v) Any other relief deemed just, proper, and/or equitable.

2 **PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE**

3
4 Dated: March 27, 2019

5 **ROBINS KAPLAN LLP**

6 By: 

7 Roman Silberfeld
8 Bernice Conn
9 Michael A. Geibelson
10 Lucas A. Messenger

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ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT G

SUM-100

SUMMONS (CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF FULLERTON, and
(LO ESTÁ DEMANDANDO EL DEMANDANTE): THE PEOPLE OF THE
STATE OF CALIFORNIA, by and through Fullerton City
Attorney Richard D. Jones

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
 (El nombre y dirección de la corte es):

San Francisco County Superior Court
 Civic Center Courthouse
 400 McAllister Street
 San Francisco, CA 94102-4515

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783

310-552-0130 310-229-5800

Lucas A. Messenger, Bar No. 217645

ROBINS KAPLAN LLP

Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

CLERK OF THE COURT

Clerk, by

(Secretario)

DE LA VEGA-NAVARRO, Rossaly

Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):

3. ☐ on behalf of (specify):

under: ☐ CCP 416.10 (corporation)

☐ CCP 416.20 (defunct corporation)

☐ CCP 416.40 (association or partnership)

☐ other (specify):

☐ CCP 416.60 (minor)

☐ CCP 416.70 (conservatee)

☐ CCP 416.90 (authorized person)

4. ☐ by personal delivery on (date):

(SEAL)

SUM-200(A)

SHORT TITLE: City of Fullerton, et al. v. Purdue Pharma
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

Page _____ of _____
 Page 1 of 1

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Attorneys for Plaintiffs City of Fullerton and
The People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

CGC-19-574867

CITY OF FULLERTON, and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Fullerton
City Attorney Richard D. Jones,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND

Case No.

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;

ENDORSED
FILED
Superior Court of California
County of San Francisco
MAR 28 2019
CLERK OF THE COURT
BY: ROSSALY DE LA VEGA
Deputy Clerk

Robins Kaplan LLP

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Attorneys for Plaintiffs City of Fullerton and
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(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

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City Attorney Richard D. Jones,

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PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
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MEMBERS OF THE RAYMOND
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- 6. FALSE ADVERTISING;**
- 7. NEGLIGENT FAILURE TO WARN;**

1 SACKLER FAMILY; MORTIMER D.A.
 2 SACKLER, an individual; KATHE A.
 3 SACKLER, an individual; IRENE
 4 SACKLER LEFCOURT, an individual;
 5 BEVERLY SACKLER, an individual and
 6 as trustee for TRUST FOR THE BENEFIT
 7 OF MEMBERS OF THE RAYMOND
 8 SACKLER FAMILY; THERESA
 9 SACKLER, an individual; DAVID A.
 10 SACKLER, an individual; CEPHALON,
 11 INC.; TEVA PHARMACEUTICAL
 12 INDUSTRIES, LTD.; TEVA
 13 PHARMACEUTICALS USA, INC.;
 14 JANSSEN PHARMACEUTICALS, INC.;
 15 JOHNSON & JOHNSON; ORTHO-
 16 MCNEIL-JANSSEN
 17 PHARMACEUTICALS, INC.; JANSSEN
 18 PHARMACEUTICA, INC.; ENDO
 19 HEALTH SOLUTIONS INC.; ENDO
 20 PHARMACEUTICALS INC.; ACTAVIS
 21 PLC; WATSON PHARMACEUTICALS,
 22 INC.; WATSON LABORATORIES, INC.;
 23 ACTAVIS PHARMA, INC.; ACTAVIS
 24 LLC; ALLERGAN PLC; ALLERGAN,
 25 INC.; ALLERGAN USA, INC.; INSYS
 26 THERAPEUTICS, INC.;
 27 MALLINCKRODT, PLC;
 28 MALLINCKRODT, LLC; CARDINAL
 HEALTH, INC.;
 AMERISOURCEBERGEN
 CORPORATION; MCKESSON
 CORPORATION; and
 DOES 1-100, inclusive,

Defendants.

8. FRADULENT TRANSFER; and

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	2
A.	The Plaintiffs.....	2
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	11
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Fullerton Through Illicit Channels.....	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Fullerton Through Illicit Channels	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Fullerton	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff City of Fullerton (hereinafter, “Fullerton”) has been particularly hard hit, causing Fullerton to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. Fullerton, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California (the “People,” and together with Fullerton, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants’ efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. Fullerton has seen increased costs of, including, but not limited to, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) Fullerton city services related to infants born with opioid-related medical conditions; (d) Fullerton city services related to children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (e) public safety connected to the opioid epidemic within Fullerton, including police,

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 emergency response services, and detention centers; (f) increased burden on Fullerton's code
2 enforcement programs; and (g) extensive clean-up of public parks, spaces, and facilities. At the
3 same time, Fullerton has seen a reduction to tax revenues caused by the epidemic created by the
4 Defendants. Almost every citizen of Fullerton has been affected. The resulting damage to Fullerton
5 was directly and foreseeably caused by Defendants' actions.

6 7. These increased costs could have been—and should have been—prevented by the
7 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
8 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
9 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
10 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
11 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
12 protecting opioids from theft, misuse, and diversion.

13 8. Instead of acting with reasonable care and in compliance with their legal duties,
14 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
15 process.

16 9. At the same time, Defendants flooded the market with false statements designed to
17 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
18 claims were false.³

19 10. Defendants' actions have not only caused significant costs, but have also created a
20 palpable climate of fear, distress, dysfunction and chaos among Fullerton residents where opioid
21 diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

22 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
23 and/or unlawful conduct.

24 **II. THE PARTIES**

25 **A. The Plaintiffs**

26 12. Fullerton, California, by and through its attorneys hereto and its City Attorney,
27

28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

1 hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the
2 State of California to protect the public from false and misleading advertising, fraudulent acts,
3 negligent acts, and a public nuisance.

4 13. Fullerton has standing to recover damage incurred because of Defendants' actions
5 and omissions. Fullerton has standing to bring actions including, *inter alia*, public nuisance claims
6 asserted under state law.

7 **B. The Manufacturer Defendants**

8 14. The Manufacturer Defendants are defined below. At all relevant times, the
9 Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of
10 commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported
11 to inform prescribers and users regarding the benefits and risks associated with the use of
12 prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have
13 manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion
14 and report suspicious orders.

15 15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of
16 Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business
17 in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation
18 with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma
19 Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

20 16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin,
21 MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States,
22 including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales
23 of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006
24 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
25 (painkillers).

26 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
27

28 ⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

California, acting by and through the California Attorney General, based principally on Purdue's direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M) and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its promotional and marketing practices regarding OxyContin at any time up to and including May 8, 2007. The People, however, do assert claims arising under California law independent of the Purdue Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"), which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the Raymond Sackler Trust.

20. Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its “specialty medicines” division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in California, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for covering certain co-pay costs.

29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s USA’s sales as its own, and its year-end report for 2012—the year immediately following the Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd. operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies’ business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in

1 New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now
 2 known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of
 3 business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen
 4 Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in
 5 Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than
 6 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's
 7 products. Upon information and belief, J&J controls the sale and development of Janssen
 8 Pharmaceutical's products and Janssen's profits inure to J&J's benefit. (together, Janssen
 9 Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc.,
 10 and J&J are referred to as "Janssen").

11 31. Janssen manufactures, promotes, sells, and distributes drugs in the United States,
 12 including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted
 13 for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold
 14 the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172
 15 million in sales in 2014.

16 32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal
 17 place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly
 18 owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal
 19 place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals
 20 Inc. are referred to collectively as "Endo").

21 33. Endo develops, markets, and sells prescription drugs, including the opioids
 22 Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In
 23 2012, opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion. Opana ER
 24 yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo's total
 25 revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,
 26 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
 27 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
 28 International Trade Co., is registered to do business in California with the California Secretary of

1 State.

2 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
3 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
4 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
5 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
6 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
7 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
8 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
9 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
10 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
11 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
12 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
13 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
14 Laboratories, Inc. are referred to as “Actavis”).

15 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
16 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
17 in the United States, including California. Actavis acquired the rights to Kadian from King
18 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
19 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
20 California Secretary of State.

21 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
22 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
23 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
24 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
25 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,
26 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
27 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
28 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in

1 California with the California Secretary of State.

2 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
3 principal place of business located in Chandler, Arizona.

4 38. Insys manufactures, promotes, sells, and distributes opioids. Insys' principal source
5 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
6 United States, including California. Subsys was indicated by the FDA for the treatment of
7 breakthrough cancer pain that other opioids could not eliminate.

8 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
9 bribe physicians with purported speaking fees for marketing and education events in exchange for
10 them prescribing Subsys for off-label uses. Insys' founder and several other former Insys executives
11 were recently indicted by federal prosecutors on racketeering charges, alleging that these
12 individuals approved and fostered fraudulent behavior against insurance companies and also
13 conspired to bribe practitioners in various states. Insys Group is registered to do business in
14 California with the California Secretary of State.

15 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
16 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
17 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
18 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
19 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt").

20 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
21 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
22 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
23 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
24 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
25 Products are registered to do business in California with the California Secretary of State.

26 42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and
27 Mallinckrodt are the "Manufacturer Defendants."
28

C. The Distributor Defendants

43. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

44. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with Fullerton and its residents, and has purposefully availed itself of the advantages of conducting business with and within Fullerton. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

45. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

46. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with Fullerton and its residents, and has purposefully availed itself of the advantages of conducting business with and within Fullerton. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

48. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with Fullerton and its residents, and has purposefully availed itself of the advantages of conducting business with and within Fullerton. McKesson is in the chain of distribution of prescription opioids. McKesson Corporation is registered to do business in California with the California Secretary of State.

49. The data which reveals and/or confirms the identity of the other wrongful opioid

distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange and their principal business consists of the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Fullerton has reason to believe each has engaged in unlawful conduct which resulted in the distribution, dispensing, and diversion of prescription opioids into Fullerton. Fullerton names each of the "Big 3" herein as defendants and places the industry on notice that Fullerton is acting to abate the public nuisance plaguing its community. Distributor Defendants have had substantial contacts and business relationships with the People. Distributor Defendants have purposefully availed themselves of business opportunities within Fullerton.

51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor Defendants."

D. The Doe Defendants

52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

53. This Court has jurisdiction over this action. Defendants are engaging in false and

misleading advertising, fraudulent acts, negligent acts, and creating or assisting in the creation of a public nuisance in Fullerton, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

54. Venue is proper in this Court because Defendants transact business in California and San Francisco County, and some of the acts complained of occurred in this venue. Furthermore, Defendant Distributor McKesson's principal place of business is in San Francisco County, and McKesson conducted business and continues to do business throughout the United States and in the State of California by regularly and continuously distributing prescription opioids throughout the State of California.

IV. GENERAL FACTUAL ALLEGATIONS

A. An Overview of the Opioid Epidemic

55. The term "opioid" includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death."⁵

56. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

57. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander, director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

1 very, very high inherent risks . . . and there's no such thing as a fully safe opioid."⁶

2 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
3 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
4 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

5 59. Before the 1990s, generally accepted standards of medical practice dictated that
6 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
7 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
8 patients' ability to overcome pain and function, as well as evidence of **greater** pain complaints as
9 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
10 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
11 generally did not prescribe opioids for chronic pain.

12 60. The market for chronic pain patients, however, was much larger, and to take
13 advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for
14 chronic pain.⁷

15 61. As described herein, Defendants engaged in conduct that directly caused doctors to
16 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
17 obligations to prevent diversion of the highly addictive substance.

18 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
19 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
20 for every person in the United States to have a bottle of pills. This represents an increase of 300%
21 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
22 were dispensed per 100 persons.

23 63. Many Americans, including Californians and residents of Fullerton, are now
24

25 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
26 Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

27 ⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times
28 (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United
 2 States, an increase of more than 22 percent over the previous year. The New York Times reported
 3 in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly
 4 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 5 a public health emergency by the President of the United States. The wave of opioid addiction was
 6 created by the increase in prescriptions.

7 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 8 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 9 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 10 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 11 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 12 80 percent of people who use heroin first misused prescription opioids.

13 65. Drug overdose deaths among all Americans increased more than 200 percent
 14 between 1999 and 2015.

15 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 16 there were 4,654 total opioid overdose deaths in 2016.⁹

17 ///

18 ///

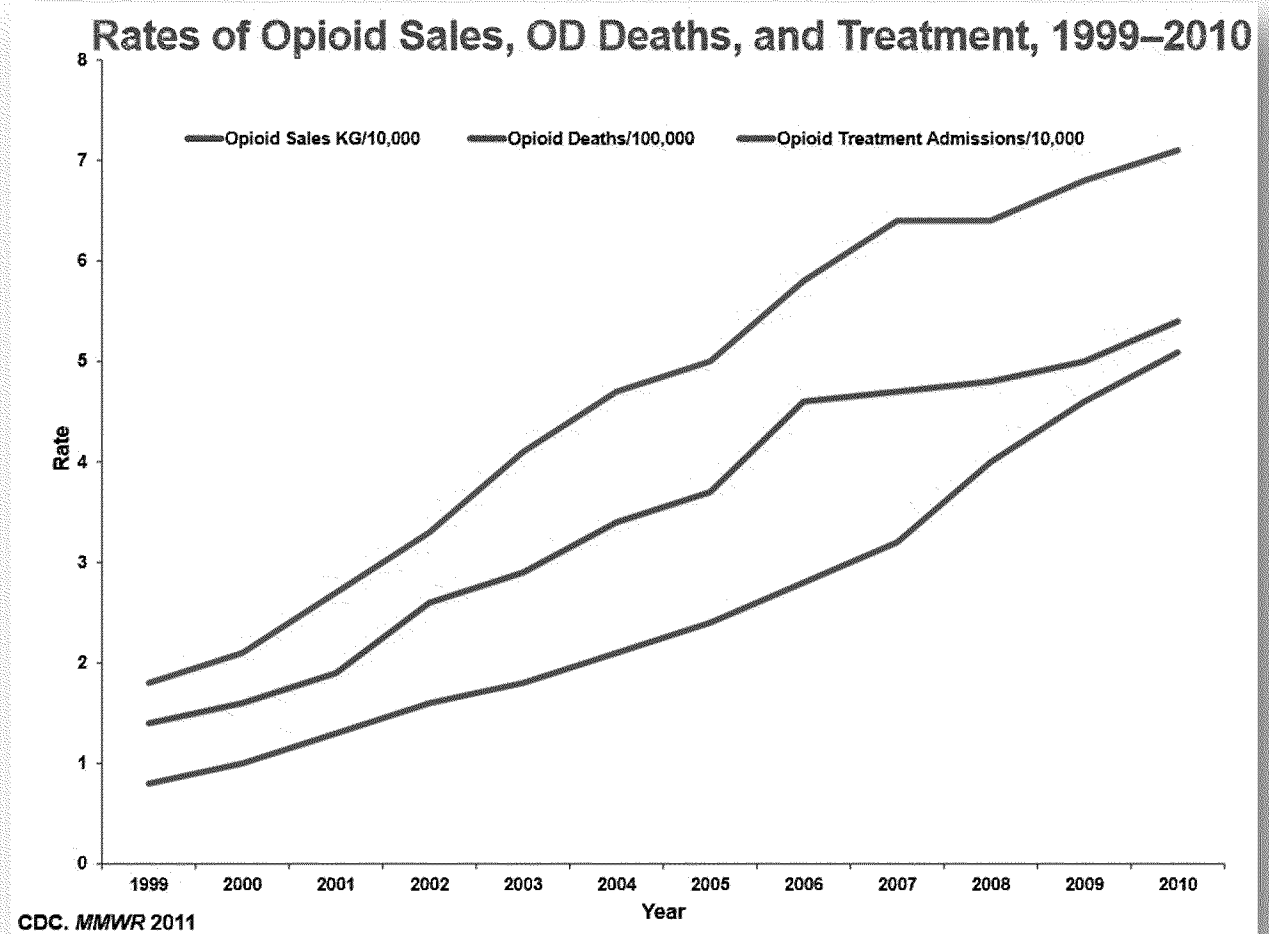
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 26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*,” N.Y.
 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

27 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
 28 <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years.

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

1 In California, 355 overdose deaths in 2016 involved heroin.¹¹

2 69. Prescription opioid abuse “is a serious national crisis that affects public health as
3 well as social and economic welfare.” The economic burden of prescription opioid misuse alone on
4 the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction
5 treatment, and criminal justice expenditures.¹²

6 **B. The Manufacturer Defendants Spread False or Misleading Information About**
7 **the Safety of Opioids**

8 70. Each Manufacturer Defendant developed a well-funded marketing scheme based on
9 deception to persuade doctors and patients that opioids can and should be used to treat chronic pain
10 without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients
11 who are much more likely to become addicted. In connection with this scheme, each Manufacturer
12 Defendant spent, and continues to spend, millions of dollars on promotional activities and materials
13 that falsely deny or minimize the risks of opioids.

14 71. The Manufacturer Defendants employed the same marketing plans and strategies,
15 and deployed the same messages in and around California, including in Fullerton, as they did
16 nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding
17 and overseeing “core message” development on a national basis. This comprehensive approach
18 ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered
19 across marketing channels—including detailing visits, speaker events, and advertising—and in
20 each sales territory. The Manufacturer Defendants consider this high level of coordination and
21 uniformity crucial to successfully marketing their prescription drugs.

22 72. To increase the impact of their deceptive marketing schemes, on information and
23 belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that
24 the Manufacturer Defendants’ messages were consistent with one another and effective across all
25

26 ¹¹ See National Institute of Drug Abuse, California Opioid Summary, available at
27 <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>,
(last accessed August 13, 2018).

28 ¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 their marketing efforts.

2 73. The deceptive marketing schemes included, among others: (a) false or misleading
3 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
4 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
5 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
6 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
7 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
8 carried a low, or no, risk of addiction.

9 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
10 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
11 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
12 of actual addiction began appearing, and advocated that the signs of addiction should be treated
13 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
14 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
15 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
16 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
17 opioid use, including the supposed ability of opioids to improve function and quality of life, even
18 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
19 claims.

20 75. These statements were not only unsupported by or contrary to the scientific
21 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
22 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
23 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

24 76. The Manufacturer Defendants began their marketing schemes decades ago and
25 continue them today.

26 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
27 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
28 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
 24

25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 29, 2017).

27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 100. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
6 unbranded advertising stated that “People who take opioids as prescribed usually do not become
7 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use.”

10 101. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 104. For example, the New York Attorney General (“NY AG”) found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to

25
26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in Fullerton and doctors treating residents of Fullerton.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

27 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

28 ²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26

27 ²³ Dr. Portenoy was a member of the board of the APF.

28 ²⁴ See Neuman & Kodjack, *supra* note 16.

1 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,
2 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

3 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
4 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
5 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
6 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
7 and policymakers had played down the risks associated with opioid painkillers while exaggerating
8 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
9 circumstances.”

10 119. Another one of the Front Groups for the Manufacturer Defendants was the American
11 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
12 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
13 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
14 marketing of chronic opioid therapy.

15 120. AAPM received substantial funding from opioid manufacturers. For example,
16 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
17 other funding) to participate. The benefits included allowing members to present educational
18 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
19 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
20 event as an “exclusive venue” for offering education programs to doctors. Membership in the
21 corporate relations council also allows drug company executives and marketing staff to meet with
22 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
23 were members of the council and presented deceptive programs to doctors who attended these
24 annual events.

25 _____
26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E.
Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last
accessed December 19, 2017).

121. On information and belief, AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA investigation.

122. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM’s website until 2011, and upon information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”) and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing practices, but they also are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,

²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 *J. Pain* 113 (2009).

1 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,
 2 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 3 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 4 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 5 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 6 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 7 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 8 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 9 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 10 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 11 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 12 disseminated in Fullerton during the relevant time period, are still available online, and were often
 13 reprinted in the Journal of Pain, which is the official journal of the American Pain Society. The
 14 Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 15 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 16 Defendants’ financial support to members of the panel.

17 126. On information and belief, the Manufacturer Defendants combined their efforts
 18 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 19 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 20 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 21 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 22 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 23 worked to address a lack of coordination among its members and develop cohesive industry
 24 messaging.

25 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 26 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 27

28 ²⁹ *Id.*

1 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
2 addiction.

3 128. Through these means, and likely others still concealed, the Manufacturer
4 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
5 opioid use.

6 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
7 **Patently False**

8 129. To convince doctors and patients that opioids carry a low risk of addiction,
9 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
10 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
11 conclusively debunked.

12 130. These misrepresentations reinforced each other and created the dangerously
13 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
14 most patients would not become addicted, and because those who were at greatest risk of addiction
15 could be readily identified and managed; (b) patients who displayed signs of addiction probably
16 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
17 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
18 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
19 inherently less addictive.

20 131. Some examples of these false and misleading claims that were made by, are
21 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 22 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
23 Back Pain, to be distributed beginning in 2003 that admitted that opioid
24 addiction is possible, but falsely claimed that it is "less likely if you have never
25 had an addiction problem." Based on Actavis's acquisition of its predecessor's
26 marketing materials along with the rights to Kadian, it appears that Actavis
27 continued to use this brochure in 2009 and beyond.
- 28 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
People Living with Pain (2007), which suggests that addiction is rare and

limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication remains available today.³⁰

- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain." This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."³¹
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Fullerton, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

133. The Manufacturer Defendants' misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication use presents serious risks, including ... opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

135. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that "most opioid drugs have '*high potential for abuse*'" and that opioids "are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." (Emphasis added.)³⁴ According to the FDA, because of the "*known* serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not to “make statements that ... opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. This prohibition did not extend to California.

138. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is *under-treated* . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

- d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long acting opioid.
- f. Details for Purdue have directed doctors and their medical staffs in California, including in Fullerton, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.
- g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which states: “Pseudo-addiction describes patient behaviors that may occur when pain is undertreated...Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.”

Deceptive Claims of Pseudoaddiction

139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents” and reported that despite the fact that Endo trained its sales representative to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk

1 Management testified to [the NY AG] that he was not aware of any research validating the
2 ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction
3 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
4 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
5 with respect to California.

6 141. The Manufacturer Defendants also falsely instructed doctors and patients that
7 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
8 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
9 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
10 general practitioners and family doctors who lack the time and expertise to closely manage higher-
11 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
12 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
13 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
14 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 15 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
16 *Family Practice* written by a doctor who became a member of Endo’s speakers
17 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
18 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
19 tools, claiming that patients at high risk of addiction could safely receive
20 chronic opioid therapy using a “maximally structured approach” involving
21 toxicology screens and pill counts.
- 22 b. On information and belief, Purdue sponsored a November 2011 webinar,
23 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
24 that screening tools, urine tests, and patient agreements prevent “overuse of
25 prescriptions” and “overdose deaths.”
- 26 c. On information and belief, as recently as 2015, Purdue has represented in
27 scientific conferences that “bad apple” patients – and not opioids – are the
28 source of the addiction crisis and that once those “bad apples” are identified,
doctors can safely prescribe opioids without causing addiction.
- d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including Fullerton the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were

³⁷ See *supra* note 35, at 7.

1 false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
 2 The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk
 3 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
 4 widely believed by doctors to detect and deter abuse—“for improving outcomes related to
 5 overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that
 6 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
 7 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
 8 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

9 143. To underplay the risk and impact of addiction and make doctors feel more
 10 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
 11 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
 12 failed to disclose the increased difficulty of stopping opioids after long-term use.

13 144. For example, on information and belief, a 2011 non-credit educational program
 14 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
 15 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

16 145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
 17 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
 18 by gradually decreasing the dose of medication during discontinuation” without mentioning any
 19 hardships that might occur.³⁸ This publication was available on APF’s website until the
 20 organization dissolved in May 2012.

21 146. Detailers for Janssen have told and continue to tell doctors in California, including
 22 Fullerton, that their patients would not experience withdrawal if they stopped using opioids.

23 **Deceptive Minimization of Opioid Withdrawal**

24 147. The Manufacturer Defendants also deceptively minimized the significant symptoms
 25 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
 26 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly

27
 28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

1 understated the difficulty of tapering, particularly after long-term opioid use.

2 148. Contrary to the Manufacturer Defendants' representations, the 2016 CDC Guideline
3 recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]"
4 to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,"
5 because "physical dependence on opioids is an expected physiologic response in patients exposed
6 to opioids for *more than a few days*." (Emphasis added.) The 2016 CDC Guideline states that
7 "more than a few days of exposure to opioids significantly increases hazards" and "each day of
8 unnecessary opioid use increases likelihood of physical dependence without adding benefit." The
9 2016 CDC Guideline further states that "tapering opioids can be especially challenging after years
10 on high dosages because of physical and psychological dependence" and highlights the difficulties,
11 including the need to carefully identify "a taper slow enough to minimize symptoms and signs of
12 opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The
13 CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of
14 different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

15 **Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk**

16 149. The Manufacturer Defendants also falsely claimed that doctors and patients could
17 increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to
18 patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer
19 Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this
20 misrepresentation, doctors would have abandoned treatment when patients built up tolerance and
21 lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that
22 were made by, and are continuing to be made by Defendants, are described below:

- 23 a. On information and belief, Actavis's predecessor created a patient brochure for
24 Kadian in 2007 that stated, "Over time, your body may become tolerant of
25 your current dose. You may require a dose adjustment to get the right amount
26 of pain relief. This is not addiction." Upon information and belief, based on
27 Actavis' acquisition of its predecessor's marketing materials along with the
28 rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for
People Living with Pain* (2007), which claims that some patients "need" a
larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in Fullerton that they should increase the dose of OxyContin, rather
than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was **no** evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in Fullerton, that Opana ER is harder to abuse and given demonstrations to nurse
22 practitioners about Opana ER’s purported abuse deterrent properties.

23
24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
[push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
[ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those statements to be false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

158. Because Orpana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.

159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse, and that its abuse deterrent properties can be defeated.

160. These statements and omissions by Purdue are false and misleading, and conflict with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 430.

27 ⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose*
 28 *epidemic*, Business Insider (Mar. 14, 2016), available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in Fullerton, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewharper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

174. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

26 _____
27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by Fullerton.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

26
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
28 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

⁵² *Id.*

misrepresentations deceived and continue to deceive doctors and patients in California, including in Fullerton, about the risks and benefits of long-term opioid use. California doctors confirm this. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. Plaintiff is informed and believes that California residents were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

192. Numerous doctors and substance abuse counselors in California note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic. Treatment centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients for opioid addiction.

193. The Manufacturer Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids caused and continue to cause doctors in California, including doctors in Fullerton, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia, rather than prescribing less addictive medications. Absent Manufacturers Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids have caused and continue to cause the prescribing and use of opioids to explode in California, including in Fullerton. Opioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per

1 year are prescribed a long-acting opioid.

2 196. In California, including Fullerton, Manufacturer Defendants' deceptive marketing
3 of the abuse-deterrent properties of their opioids during the past few years has been particularly
4 effective. For example, one survey reports that pain specialists were more likely to recognize that
5 OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those
6 properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using
7 more of it than those who did not know it was an AD opioid. Although sales of AD opioids still
8 represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they
9 represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in
10 opioid sales revenue in 2015).

11 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 198. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 199. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 200. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 201. Diversion can occur at any point in the opioid supply chain.

4 202. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 205. Opioid diversion occurs at an alarming rate in the United States.

23 206. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 **210.** In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 211. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 212. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for Fullerton and the people therein.

25 213. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

1 214. Thus, all opioid distributors are required to maintain effective controls against
2 opioid diversion. They are required to create and use a system to identify and report to the California
3 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
4 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
5 and/or orders of unusual frequency. To comply with these requirements, distributors must know
6 their customers, must conduct due diligence, must report suspicious orders, and must terminate
7 orders if there are indications of diversion.

8 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
9 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
10 their obligations under the CSA.

11 216. Under the CSA, anyone authorized to handle controlled substances must track
12 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
13 automated drug reporting system that records and monitors the flow of Schedule II controlled
14 substances from the point of manufacture through distribution to the point of sale. ARCOS
15 accumulates data on distributors' controlled substances and transactions, which are then used to
16 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
17 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
18 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
19 and current record of each substance manufactured, imported, received, sold, delivered, exported,
20 or otherwise disposed of.

21 217. Plaintiff does not bring causes of action based on violations of federal statutes and
22 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
23 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
24 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
25 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
26 prescription opioids.

1 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
 2 **Opioids to Fullerton Through Illicit Channels**

3 218. The Distributor Defendants have been and continue to be well-aware of problems
 4 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance
 5 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
 6 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
 7 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
 8 that the DEA also provides distributors with data on controlled substance distribution patterns and
 9 trends, including data on the volume and frequency of orders and the percentage of controlled
 10 versus non-controlled purchases. The distributors are also given case studies, legal findings against
 11 other registrants, and ARCOS profiles of their customers whose previous purchases may have
 12 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
 13 Defendants should look for in order to identify potential diversion.

14 219. Since 2007, the DEA has hosted at least five conferences to provide registrants with
 15 updated information about diversion trends and regulatory changes that affect the drug supply
 16 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
 17 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
 18 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
 19 also request clarification on DEA policies, procedures, and interpretations of the CSA and
 20 implementing regulations.

21 220. Since 2008, the DEA also has participated in numerous meetings and events with
 22 the legacy Healthcare Distribution Management Association (HDMA), now known as the
 23 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
 24 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
 25 guidance to the association concerning suspicious order monitoring, and the association has
 26 published guidance documents for its members on suspicious order monitoring, reporting
 27 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
 28 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 Fullerton and its residents. Each Distributor Defendant knew or should have known that the opioids
7 reaching Fullerton were not being consumed for medical purposes and that the amount of opioids
8 flowing to Fullerton was far in excess of what could be consumed for medically necessary purposes.

9 232. The Distributor Defendants negligently or intentionally failed to adequately control
10 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
11 substances would have anticipated the danger of opioid diversion and protected against it by, for
12 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
13 greater oversight, security, and control of supply channels; (c) looking more closely at the
14 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
15 amounts greater than the populations in those areas would warrant; (d) investigating demographic
16 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
17 Fullerton; (e) providing information to pharmacies and retailers about opioid diversion; and (f) in
18 general, simply following applicable statutes, regulations, professional standards, and guidance
19 from government agencies and using a little bit of common sense.

20 233. On information and belief, the Distributor Defendants made little to no effort to visit
21 the pharmacies servicing the areas around Fullerton to perform due diligence inspections to ensure
22 that the controlled substances the Distributor Defendants had furnished were not being diverted to
23 illegal uses.

24 234. On information and belief, the compensation the Distributor Defendants provided
25 to certain of their employees was affected, in part, by the volume of their sales of opioids to
26 pharmacies and other facilities servicing the areas around Fullerton, thus improperly creating
27 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid
28 abuse.

1 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
2 flooding the market in and around Fullerton with highly addictive opioids would allow opioids to
3 fall into the hands of children, addicts, criminals, and other unintended users.

4 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
5 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
6 and death. It was also reasonably foreseeable that many of these injuries would be suffered by
7 Fullerton residents, and that the costs of these injuries would be borne by Fullerton.

8 237. The Distributor Defendants knew or should have known that the opioids being
9 diverted from their supply chains would contribute to the opioid epidemic faced by Fullerton, and
10 would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
11 addiction, demand, illegal transactions, economic ruin, and human tragedy.

12 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
13 and around Fullerton, but, on information and belief, they nevertheless persisted in a pattern of
14 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
15 with such frequency that they knew or should have known these commonly abused controlled
16 substances were not being prescribed and consumed for legitimate medical purposes.

17 239. The use of opioids by Fullerton residents who were addicted or who did not have a
18 medically necessary purpose could not have occurred without the knowing cooperation, assistance,
19 or negligent failure to act of and by the Distributor Defendants. If the Distributor Defendants
20 adhered to effective controls to guard against diversion, Fullerton and its residents would have
21 avoided significant injury.

22 240. The Distributor Defendants made substantial profits over the years based on the
23 diversion of opioids into Fullerton. The Distributor Defendants knew that Fullerton would be
24 unjustly forced to bear the costs of these injuries and damages.

25 241. The Distributor Defendants' intentional distribution of excessive amounts of
26 prescription opioids showed an intentional or reckless disregard for the safety of Fullerton and its
27 residents. Their conduct poses a continuing threat to the health, safety, and welfare of Fullerton.

28 242. The state laws at issue here are public safety laws.

1 243. The Distributor Defendants' violations constitute prima facie evidence of
2 negligence under state law.

3 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
4 **of Opioids to Fullerton Through Illicit Channels**

5 244. The same legal duties to prevent diversion, and to monitor, report, and prevent
6 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
7 were also legally required of the Manufacturer Defendants under California law.

8 245. In addition to a common law duty to exercise reasonable care in the promotion and
9 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
10 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
11 determined by the Board. *See* 16 CCR 1782.

12 246. On information and belief, for over a decade the Manufacturer Defendants have
13 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
14 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
15 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
16 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
17 Manufacturer Defendants breached their duties under state law.

18 247. The Manufacturer Defendants had access to and possession of the information
19 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
20 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
21 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
22 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
23 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
24 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
25 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
26 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer
27 Defendants built receipt of this information into the payment structure for the opioids provided to
28 the opioid distributors.

248. The Manufacturer Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Fullerton.

F. The Defendants Knowingly Profit from an Interstate Opioid Crisis

249. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state, city, and county lines in a variety of ways.

250. First, prescriptions written in one state would, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another.

251. When authorities in one state cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of regulatory oversight created a fertile ground for pill mills. Residents of many states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

252. The facts surrounding numerous criminal prosecutions illustrate this common practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught flying to California in attempts to obtain additional sources of supply for their drug operation which consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

253. In another example, a man from Warren County, Ohio, who was sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone

⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

⁵⁹ Andrew Welsh-Huggins, Associated Press, 'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

1 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
2 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
3 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
4 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
5 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

6 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
7 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
8 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
9 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
10 customers were from other states.⁶³

11 255. In yet another case, defendants who operated a pill mill in south Florida within
12 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
13 transported oxycodone back to the area for both use and distribution by local drug trafficking
14 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
15 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
16 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
17 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
18 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
19 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the

20 _____
21 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
<http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
22 accessed July 25, 2018).

23 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
24 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

25 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead*
Guilty to Operating a “Pill Mill” in Lilburn, Georgia (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
26 accessed July 25, 2018).

27 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists*
Convicted for Illegally Dispensing to Patients of a Pill Mill (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
28 [patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

1 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
2 Kentucky residents.”⁶⁵

3 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
4 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
5 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
6 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
7 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
8 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
9 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
10 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
11 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

12 257. While the I-75 corridor was well utilized, prescription tourists also came from other
13 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
14 mills come from as far away as Arizona and Nebraska.⁷⁰

15 258. Similar pipelines developed in other regions of the country. For example, the I-95
16 corridor was another transport route for prescription pills. As the director of the Maine Drug
17 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
18 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
19 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
20

21 ⁶⁵ *Id.* at 861.

22 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s
Deadliest Drug Epidemic* 171 (2016).

23 ⁶⁷ *Id.* at 172

24 ⁶⁸ *Id.* at 171

25 ⁶⁹ *Id.*

26 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
Sale of Painkillers, NBC News, available at [http://www.nbcnews.com/id/48111639/ns/usnews-
crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71](http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71)
27 (last accessed July 25, 2018).

28 ⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
Bangor Daily News (March 9, 2012), available at [http://bangordailynews.com/
2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running](http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running)
(last accessed July 25, 2018)

1 Ohio, and Kentucky.

2 259. Along the west coast, over a million pills were transported from the Lake Medical
3 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²
4 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
5 Everett-based dealer who received the pills from southern California wore a diamond necklace in
6 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
7 OxyContin—connecting Los Angeles and Washington state.

8 260. Defendants certainly were aware, or should have been aware, that pill mills from
9 around the country were pushing its products. Defendants purchased nationwide, regional, state,
10 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
11 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
12 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
13 compute, and track their competitors' sales, and to compare and analyze market share information.

14 261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
15 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
16 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
17 regarding competing drugs, and analyzed the market share of those drugs.

18 262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
19 rewarded sales representatives who happened to have pill mills within their territories, enticing
20 those representatives to look the other way even when their in-person visits to such clinics should
21 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
22 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
23 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
24 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric
25 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
26

72 Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

73 *Id.*

1 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
2 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
3 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
4 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

5 ⁷⁴

6 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
7 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
8 sales representative "it was packed with a line out the door, with people who looked like gang
9 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
10 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
11 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
12 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
13 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
14 2010 to inform the authorities.

15 264. Abundant evidence, thus, establishes that prescription opioids migrated between
16 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
17 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
18 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
19 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
20 prescription opioid pills were hard to get in one area, they migrated from another. The
21 manufacturers and distributors were fully aware of this phenomenon and profited from it.

22 265. Defendants each knew or should have known that opioid diversion and abuse was
23 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide
24 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and

25 _____
26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

1 allowed to continue the unlawful diversion of opioids into Fullerton.

2 **G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the**
3 **Harm Alleged Herein and Substantial Damages**

4 266. As the Manufacturer Defendants' efforts to expand the market for opioids increased,
5 so have the rates of prescription and the sale of their products, as well as the rates of opioid-related
6 substance abuse, hospitalization, and death among Fullerton residents and across the nation.
7 Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of
8 opioids into communities like Fullerton, fueling the epidemic.

9 267. There is a "parallel relationship between the availability of prescription opioid
10 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
11 associated adverse outcomes."⁷⁷

12 268. Opioids are widely diverted and improperly used, and the widespread use of the
13 drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

14 269. The epidemic is "directly related to the increasingly widespread misuse of powerful
15 opioid pain medications."⁷⁹

16 270. The increased abuse of prescription opioids—along with growing sales—has
17 contributed to a large number of overdoses and deaths.

18 271. As shown above, the opioid epidemic has escalated in Fullerton with devastating
19 effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants'
20 increased distribution of opioids.

21 272. Because of the well-established relationship between the use of prescription opioids
22 and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to
23 Fullerton and areas from which opioids are being diverted to Fullerton, has caused the opioid
24 epidemic to include heroin addiction, abuse, and death.

25 273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public
26

27 ⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N.
Eng. J. Med. 241 (2015).

28 ⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

1 health and safety in Fullerton.

2 274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and
3 safety in Fullerton.

4 275. Defendants repeatedly and purposefully breached their duties under state law, and
5 such breaches are direct and proximate causes of, and/or substantial factors leading to, the
6 widespread diversion of prescription opioids for nonmedical purposes in Fullerton.

7 276. The unlawful diversion of prescription opioids is a direct and proximate cause of,
8 and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction,
9 morbidity, and morality in Fullerton. This diversion and the resulting epidemic are direct causes of
10 foreseeable harms incurred by Fullerton and residents of Fullerton.

11 277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past
12 and continuing, economic damages for which Fullerton seeks relief, as alleged herein. Fullerton
13 also seeks the means to abate the epidemic created by the Defendants.

14 278. Fullerton seeks economic damages from the Defendants as reimbursement for the
15 costs associated with past efforts to eliminate the hazards to public health and safety.

16 279. Fullerton seeks economic damages from the Defendants to pay for the costs to
17 permanently eliminate the hazards to public health and safety and abate the public nuisance.

18 280. Fullerton seeks economic damages from the Defendants to pay for the reduction to
19 tax revenues caused by the epidemic created by the Defendants.

20 281. To eliminate the hazard to public health and safety, and abate the public nuisance, a
21 "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

22 282. A comprehensive response to this crisis must focus on preventing new cases of
23 opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective
24 opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

25 _____
26 ⁸⁰ Rudd, *supra* note 51.

27 ⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An*
28 *Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at
https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed January 8, 2018).

1 283. The community-based problems require community-based solutions that have been
2 limited by budgetary constraints.

3 284. Having profited enormously through the aggressive sale, misleading promotion, and
4 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
5 financial burdens their conduct has inflicted upon Fullerton.

6 285. The opioid epidemic still rages because the fines and suspensions imposed by the
7 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
8 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
9 registration numbers and when one facility is suspended, they simply ship from another facility.

10 286. The Defendants have abandoned their duties imposed by the law, taken advantage
11 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
12 Fullerton.

13 287. In the course of conduct described in this Complaint, Defendants have acted with
14 oppression, fraud, and malice, both actual and presumed.

15 **H. The Impact of Opioid Abuse on Fullerton**

16 288. Defendants' creation, through false and misleading advertising and a failure to
17 prevent diversion, of a virtually limitless opioid market has significantly harmed Fullerton and
18 resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
19 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
20 abused come, directly or indirectly, through doctors' prescriptions.

21 289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
22 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
23 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
24 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
25 associated with the consumption of a counterfeit version of the prescription drug Norco
26 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has
27 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
28 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.

1 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further
2 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
3 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
4 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
5 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
6 related overdoses, with 55% of those resulting from prescription opioids.

7 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
8 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
9 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
10 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
11 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

12 291. Even Fullerton's youngest residents bear the consequences of the opioid abuse
13 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
14 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
15 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
16 Many Fullerton women have become addicted to prescription opioids and have used these drugs
17 during their pregnancies. As a result, many Fullerton infants suffer from opioid withdrawal and
18 Neonatal Abstinence Syndrome ("NAS").⁸⁵

19 292. The impact of NAS can be life-long. Most NAS infants are immediately transferred
20

21 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
22 *year*, LA Times (Oct. 27, 2014), available at <http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html> (last accessed December 21, 2017).

23 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
24 *The Opioid Crisis in Indian Country*, at 37, available at
25 <https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US, 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

26 ⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
21, 2017).

27 ⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
28 *Syndrome*, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at
<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require
2 an emergency evacuation for care to save the infant's life. Such emergency transportation can cost
3 thousands of dollars for each occurrence.

4 293. Many NAS infants have short-term and long-term developmental issues that prevent
5 them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and
6 digestive issues; some are unable to attend full days of school. These disabilities follow these
7 children through elementary school and beyond.

8 294. Many of the parents of these children continue to relapse into prescription opioid
9 use and abuse. As a result, many of these children are placed in foster care or adopted.

10 295. Opioid addiction is now the primary reason that Californians seek substance abuse
11 treatment, and admissions to drug treatment facilities in California more than doubled from
12 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one
13 facility in northern California, up to 90% – started on legal opioid prescriptions.

14 296. The explosion in opioid prescriptions and use caused by Defendants has led to a
15 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
16 overdoses and deaths as well as devastating social and economic consequences. This public health
17 crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable
18 enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]”
19 and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each
20 Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting
21 worse.

22 297. There is little doubt that each Defendant's deceptive marketing and distribution
23 scheme has precipitated this public health crisis in California, including Fullerton, by dramatically
24 increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a
25 source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created
26 a population of patients physically and psychologically dependent on them (the demand). And when
27 those patients can no longer afford or legitimately obtain opioids, they often turn to the street to
28 buy prescription opioids or even heroin.

1 298. The effects of Defendants' deceptive marketing and distribution scheme has further
2 impacted Plaintiff in a foreseeable way such that Fullerton must devote increased resources to the
3 burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For
4 example, tax dollars are required to maintain public safety of places where the addicted homeless
5 attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight
6 the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
7 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
8 *aureus* (MRSA) are spread by opioid abuse.

9 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
10 have recruited addicts nationally with false and misleading promises of the medically supervised
11 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
12 effective rehabilitation available in beautiful California communities, including Fullerton. These
13 for-profit rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations
14 revealed that many have provided substandard care including use of physicians who have had their
15 license revoked, operating staffs which do not actually supervise patients, and facilities that do not
16 operate programs for addicts. Instead these facilities bring addicts to California, provide
17 substandard care as long as there are third party payments available, and then throw them out of
18 the facilities to be homeless. These addicts brought to California, including Fullerton, by the
19 substandard rehab industry, have further contributed to the public's burden by discharging addicted
20 homeless into the community who require further care and rehabilitation at the public's expense,
21 and who commit crimes in California in order to further feed their addiction. The manufacturer and
22 distributor Defendants were aware at all relevant times when they deceptively marketed their
23 products as non-addictive that such addiction would be highly difficult to overcome. Defendants
24 knew or should have known that municipalities, including Fullerton, would bear the burden of costs
25 associated with rehabilitation business of all types.

26 300. The role of Defendants' deceptive marketing and distribution scheme in causing this
27 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
28 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora

1 Volkow explained that “aggressive marketing by pharmaceutical companies” is “likely to have
2 contributed to the severity of the current prescription drug abuse problem.” And in August 2016,
3 the former U.S. Surgeon General expressly connected the “urgent health crisis” to “heavy
4 marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids
5 are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment
6 specialists, and law enforcement and public health officials confirm that prescription opioids
7 lawfully prescribed by doctors have fueled this epidemic.

8 301. Absent each Defendant’s deceptive marketing scheme and improper distribution,
9 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
10 the opioid epidemic that now exists would have been averted or much less severe.

11 302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
12 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
13 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
14 only engaged in false advertising, they have also created or assisted in the creation of a public
15 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the
16 present is part of its deceptive marketing and distribution scheme and subjects that Defendant to
17 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
18 *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual
19 obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance
20 of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

21 303. Accordingly, Defendants’ conduct, both individually and collectively, has violated
22 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
23 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Fullerton does not seek to limit the
24 ability of doctors in California to prescribe opioids. Fullerton does not ask this Court to weigh the
25 risks and benefits of long-term opioid use. Instead, Fullerton seeks an order requiring Defendants
26 to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations,
27 and to abate the public nuisance they have created. To redress and punish Defendants’ previous and
28 current violations of law that cause and continue to cause harm to Fullerton, Plaintiff seeks a

1 judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law.

2 304. By this action, Fullerton further seeks to recoup tax dollars spent already for the
3 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
4 impact on this county and its communities, and to abate the opioid nuisance so Fullerton will not
5 be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
6 wrongful conduct as alleged herein.

7 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
8 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
9 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
10 California spiked by 34% from 2011 to 2013.

11 306. Opioid abuse also contributes to a range of social problems including physical and
12 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
13 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
14 unemployment, and despair. More and more Fullerton resources are needed to combat these
15 problems. The prescription opioid crisis also diminishes Fullerton's available workforce, decreases
16 productivity, increases poverty, and requires greater governmental expenditures by Fullerton.

17 307. The prescription opioid crisis has directly financially injured Fullerton. The crisis
18 has led to an increased demand for, *inter alia*, security services (such as police, EMS, detention),
19 child protective services, health services, clean-up services, and legal services. Fullerton has also
20 had to hire additional staff and expend additional resources to manage the demand.

21 308. Fullerton's medical services have seen an increase in opioid-related health problems
22 among Fullerton residents, including, but not limited to, infants born with opioid-related medical
23 conditions. This has resulted in increased demand and increased expenses.

24 309. Fullerton has also suffered substantial financial damages in the form of lost
25 productivity of Fullerton employees and residents, lost economic activity, lost reputation and good
26 will, and the lost opportunity for growth. These damages have been suffered and continue to be
27 suffered directly by Fullerton.

28 310. Many patients who become addicted to opioids will lose their jobs. Some will lose

1 their homes and their families. Some will get treatment and fewer will successfully complete it;
 2 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
 3 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
 4 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
 5 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
 6 drug transactions; or dying from opioid-induced heart or neurological disease.

7 311. Fullerton also has suffered substantial financial damages in the form of lost taxes
 8 paid by its residents and businesses as a result of lost earnings and productivity.

9 312. While the use of opioids has taken an enormous toll on Fullerton and its residents,
 10 Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in
 11 revenue for drug companies like the Defendants. Indeed, on information and belief, each Defendant
 12 experienced a material increase in sales, revenue, and profits from the unlawful conduct described
 13 above.

14 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
 15 **Asserting Statutes of Limitations As Defenses**

16 313. Defendants' conduct has continued from the early 1990s through today and remains
 17 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
 18 continuous injury. The damages have not occurred all at once but have continued to occur and have
 19 increased as time progresses. The tort is not completed nor have all the damages been incurred until
 20 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
 21 public nuisance remains unabated.

22 314. Defendants are equitably estopped from relying upon a statute of limitations defense
 23 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
 24 assure the public that they were undertaking efforts to comply with their obligations under the
 25 controlled substances laws, all with the goal of continuing to generate profits.

26 315. For example, a Cardinal Health executive claimed that it uses "advanced analytics"
 27 to monitor its supply chain, and assured the public it was being "as effective and efficient as
 28

possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”⁸⁷

317. Defendants, through their trade associations, filed an amicus brief that represented that Defendants took their duties seriously, complied with their statutory and regulatory responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

318. Defendants purposely concealed their wrongful conduct, including by assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their behavior by providing the public with false information about opioids and have continued to use Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct is continuing to this day.

319. Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which will confirm their identities and the extent of their wrongful and illegal activities.

320. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a distributor’s license was raised.

⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html (last accessed December 21, 2017).

⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, (Dec. 22, 2016), available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed December 21, 2017).

⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4, 2016).

⁸⁹ See Higham and Bernstein, *supra* note 53.

1 321. In addition, the Defendants fraudulently attempted to convince the public that they
2 were complying with their legal obligations and working to curb the opioid epidemic.

3 322. Because the Defendants concealed the facts surrounding the opioid epidemic,
4 Fullerton did not know of the existence or scope of the Defendants' misconduct, and could not have
5 acquired such knowledge earlier through the exercise of reasonable diligence.

6 323. Defendants intended that their false statements and omissions be relied upon,
7 including by Fullerton, and its residents.

8 324. Defendants knew of their wrongful acts and had material information pertinent to
9 their discovery, but concealed that information from the public, including Fullerton, and its
10 residents. Only Defendants knew of their widespread misinformation campaign and of their
11 repeated, intentional failures to prevent opioid diversion.

12 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
13 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
14 opioid crisis have only recently come to light.

15 326. Defendants had actual knowledge that their conduct was deceptive, and they
16 intended it to be deceptive.

17 327. Fullerton was unable to obtain vital information regarding these claims absent any
18 fault or lack of diligence on Fullerton's part.

19 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

20 **A. The Marketing Scheme**

21 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
22 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
23 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
24 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
25 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
26 long-term, chronic pain. Through their personal relationships, the members of this marketing
27 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
28 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the

1 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

2 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
3 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
4 made misleading statements and misrepresentations about opioids that downplayed the risk of
5 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
6 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
7 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
8 of an invented condition the Manufacturer Defendants named “pseudoaddiction”; (d) withdrawal
9 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
10 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
11 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
12 formulations provide a solution to opioid abuse.

13 330. The marketing scheme devised, implemented and conducted by the Manufacturer
14 Defendants was designed to ensure that they unlawfully increased their sales and profits through
15 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
16 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
17 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
18 network as described above.

19 331. There was regular communication between the Manufacturer Defendants, Front
20 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
21 exchanged. Typically, the coordination, communication and payment occurred, and continues to
22 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
23 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
24 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
25 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
26 each agreed and took actions to hide the scheme and continue its existence.

27 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants’
28 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front

1 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
2 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
3 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
4 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
5 their members and constituents. By failing to disclose this information, Front Groups perpetuated
6 the marketing scheme, and reaped substantial benefits.

7 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
8 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
9 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
10 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
11 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
12 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
13 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
14 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
15 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
16 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
17 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
18 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

19 334. As public scrutiny and media coverage focused on how opioids ravaged
20 communities in California and throughout the United States, the Front Groups and KOLS did not
21 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
22 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
23 using opioids for chronic pain.

24 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
25 categories of activities in furtherance of the marketing scheme. As described herein, the
26 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
27 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
28 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to

1 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
2 and (d) efforts to limit prescriber accountability.

3 336. In addition to disseminating misrepresentations about the risks and benefits of
4 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
5 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
6 criticized or undermined the CDC Guidelines which represented “an important step – and perhaps
7 the first major step from the federal government - toward limiting opioid prescriptions for chronic
8 pain.”

9 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
10 the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not
11 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
12 of the individuals who participated in the construction of these guidelines.”

13 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
14 president, stating “that the CDC guideline makes disproportionately strong recommendations based
15 upon a narrowly selected portion of the available clinical evidence.”

16 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
17 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
18 “neutral” and more “scientific” than the Manufacturer Defendants themselves. Without the work
19 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
20 scheme could not have achieved its common purpose.

21 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to
22 be prescribed and used for chronic pain throughout Fullerton, and the epidemic continues to injure
23 Plaintiff, and consume the resources of Plaintiff’s emergency health services and law enforcement
24 systems.

25 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
26 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
27 in the object of the scheme, and functioned within a structure designed to effectuate the scheme’s
28 purpose.

B. The Distribution Scheme

342. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to “a categorical denial of any criminal behavior or intent.”⁹⁰ Defendants’ actions went far beyond what could be considered ordinary business conduct. For more than a decade, the Distributor Defendants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

343. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, California enacted California Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems to detect and report such activity.

344. If morality and the law did not suffice, competition dictates that the Distributor Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so.

345. The Distributor Defendants’ scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for state authorities or the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the

⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, the Distributor Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

346. As described above, at all relevant times, the Distributor Defendants conspired together for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

347. At all relevant times, as described above, the Distributor Defendants exerted control over, conducted and/or participated in distribution scheme by fraudulently claiming that they were complying with their duties under California law to report suspicious orders and to maintain systems to detect and report such activity.

348. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators’ ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁹¹

⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement*

349. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

350. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

351. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

352. Each Defendant's conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under California Business & Professions Code § 17536.

While the Opioid Epidemic Grew Out of Control, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 353. As a members of the boards of various Purdue entities, the Sacklers oversaw all
2 aspects of Purdue's marketing and promotion of opioid products. As board members who were
3 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
4 known, of Purdue's deceptive marketing tactics of opioid products.

5 354. The Sackler Defendants also were aware of specific examples of deceptive
6 marketing through receipt of call note reviews in their capacities as board members. On information
7 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
8 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
9 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

10 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
11 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
12 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
13 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

14 356. By 2006, prosecutors at the United States Department of Justice found damning
15 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
16 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
17 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
18 events and side effects than other pain medications.

19 357. As members of the family that owns Purdue, the Sackler Defendants personally
20 benefitted from the success of OxyContin. At various points, as directors, they approved the
21 distribution of funds from Purdue to shareholders, including themselves and their extended family.

22 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
23 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
24 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
25 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
26 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
27 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
28 the opioid related liabilities of the companies from which they were transferred.

359. Plaintiff is informed and believes that due to the billions of dollars in profits that have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly profited and received the benefits of that wrongdoing.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)

360. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 359 above as if set forth fully herein.

361. California Civil Code § 3479 provides that “anything which is injurious to health ... or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property ... is a nuisance.”

362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

363. California Civil Code § 3490 states that “no lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right.”

364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought by Fullerton to abate the public nuisance created by the Defendants.

365. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Fullerton in violation of California Civil Code §§ 3479 and 3480.

366. The public nuisance is substantial and unreasonable. Defendants’ actions caused and continue to cause the public health epidemic described above in Fullerton, and that harm outweighs any offsetting benefit.

1 367. Defendants knew and should have known that their promotion and distribution of
2 opioids was false and misleading and that their deceptive marketing scheme would create or assist
3 in the creation of the public nuisance—i.e., the opioid epidemic.

4 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
5 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
6 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
7 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
8 so widespread, and the opioid epidemic that now exists would have been averted or much less
9 severe.

10 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
11 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
12 can be abated.

13 370. Each Defendant is liable for public nuisance because its conduct at issue is
14 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
15 endangers the safety, health, morals, comfort, or repose of a considerable number of people in
16 Fullerton. Defendants' conduct is also indecent or offensive to the senses, and constitutes an
17 obstruction to the free use of property sufficient to constitute an interference with the people of
18 Fullerton's comfortable enjoyment of life or property.

19 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
20 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
21 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
22 unreasonable interference with Fullerton and its residents' public rights, including, but not limited
23 to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free
24 from disturbance and reasonable apprehension of danger to person or property.

25 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
26 interfered with Fullerton and its residents' public rights by, *inter alia*, engaging in a promotion and
27 marketing scheme that pushed the use of opioids for indications not federally approved, and by
28 circulating false and misleading information concerning their risks, benefits, and superiority, and/or

1 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
2 Defendants failed to comply with federal law.

3 373. Defendants have also unlawfully and intentionally distributed opioids or caused
4 opioids to be distributed within and without Fullerton absent effective controls against diversion.
5 Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain
6 effective controls against diversion include Defendants' failure to effectively monitor for
7 suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

8 374. Defendant's unreasonable interference with Fullerton residents' public rights
9 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
10 expenditures to combat and address these harms. These damages have been suffered and continue
11 to be suffered directly by Fullerton and its residents.

12 375. Defendants' actions have also created a palpable climate of fear, distress,
13 dysfunction and chaos among residents of Fullerton where opioid diversion, abuse, and addiction
14 are prevalent and where diverted opioids are used frequently. Specifically, Defendants conduct has
15 caused, among other things, (a) routine separation of children from their parents who have fallen
16 victim to easy access to opioids and/or related crime; (b) children to have easy access and to become
17 addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for
18 loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces
19 and property; (e) property crimes throughout Fullerton; (f) employers to lose the value of productive
20 and healthy employees; (g) increased public health and safety costs; (h) a reduction in potential
21 property values within Fullerton; (i) harm to families and their residential neighborhoods and
22 peaceful enjoyment of their properties due to the influx of people suffering from addiction caused
23 by Defendants' misconduct; and (g) a decrease in tax revenues for Fullerton.

24 376. The impact of Defendants' conduct on Fullerton is of a continuing nature.
25 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

26 377. Defendants knew or should have known that their actions would lead to the national
27 opioid epidemic and to the resulting injuries to the public rights of Fullerton.

28 378. Fullerton has sustained a special and peculiar injury because its damages include,

1 *inter alia*, health service expenditures, public safety expenditures, payment of opioid addiction
2 treatment, decreased tax revenues, a reduction in potential property values, residents' use and
3 enjoyment of their properties, and other costs related to opioid addiction treatment, emergency
4 medical services, and overdose prevention.

5 379. The externalized risks associated with Defendants' nuisance-creating conduct as
6 described herein greatly exceed the internalized benefits.

7 380. Defendants' actions are a direct and proximate contributing cause of the opioid
8 epidemic and the injuries to the public rights of Fullerton and its residents.

9 381. Defendants, individually and collectively, are at the very least, a substantial factor
10 in causing the national opioid epidemic and of the injuries to Fullerton and its residents.

11 382. The injuries to the public rights of Fullerton and its residents are indivisible injuries.

12 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
13 if unabated, will continue to cause an unreasonable interference with public rights of Fullerton and
14 its residents.

15 384. Defendants' conduct is ongoing and persistent, and Fullerton seeks all damages
16 flowing from Defendants' conduct. Fullerton seeks economic losses (direct, incidental, and/or
17 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
18 above. Fullerton does not seek damages for the wrongful death, physical personal injury, or
19 emotional distress caused by Defendants' actions.

20 385. Pursuant to Code of Civil Procedure § 731, Fullerton requests an order providing
21 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
22 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

23 **SECOND CAUSE OF ACTION**
24 **(Fraud – Against All Defendants)**

25 386. Plaintiff realleges and incorporates herein by reference each and every allegation in
26 paragraphs 1 through 384 above as if set forth fully herein.

27 387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set
28 forth herein

1 388. The Defendants made fraudulent misrepresentations and omissions of material fact.
2 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
3 were intended to induce reliance.

4 389. Those misrepresentations and omissions were known to be untrue by the
5 Defendants, or were recklessly made.

6 390. As alleged herein, the Manufacturer Defendants engaged in false representations
7 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
8 dangers of abuse, and the risks of addiction.

9 391. As alleged herein, Defendants made false statements and/or omissions regarding
10 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
11 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
12 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
13 opioids, within Fullerton.

14 392. Defendants made those misrepresentations and omissions in an intentional effort to
15 deceive Fullerton and its residents, despite the Defendants' knowledge of the dangers of such use
16 of prescription opioids.

17 393. In addition and independently, Defendants had a duty not to deceive Plaintiff
18 because Defendants had in their possession unique material knowledge that was unknown, and not
19 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

20 394. The Defendants continued making those misrepresentations, and failed to correct
21 those material omissions, despite repeated regulatory settlements and publications demonstrating
22 the false and misleading nature of the Defendants' omissions and/or claims.

23 395. While Defendants had a duty to disclose the above-referenced material facts, they
24 nevertheless concealed them. These false representations and concealed facts were material to the
25 conduct and actions at issue. Defendants made these false representations and concealed facts with
26 knowledge of the falsity of their representations and did so with the intent of misleading Fullerton,
27 its residents, the public, and persons on whom these entities relied.

28 396. Defendants intended and had reason to expect under the operative circumstances

1 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
2 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
3 and that these entities would act or fail to act in reasonable reliance thereon.

4 397. Fullerton, its residents, and others, did in fact rightfully, reasonably, and justifiably
5 rely on Defendants' representations and/or concealments, both directly and indirectly.

6 398. For instance, doctors, including those serving Fullerton and its residents, relied on
7 the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
8 Patients, including residents of Fullerton, relied on the Defendants' misrepresentations and
9 omissions in taking prescription opioids for chronic pain relief.

10 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
11 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
12 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
13 effective response to the opioid crisis.

14 400. Defendants' misconduct alleged in this case is ongoing and persistent.

15 401. Fullerton has experienced an unprecedented opioid addiction and overdose epidemic
16 leading to increased costs for, *inter alia*, emergency services, treatment services, security services,
17 and lost productivity to Fullerton's workforce.

18 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
19 result of Defendants' fraudulent conduct.

20 403. As a direct and foreseeable consequence of Defendants' fraud, Fullerton has
21 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
22 opioid addiction treatment and its secondary consequences in excess of those Fullerton would have
23 otherwise incurred.

24 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
25 fraudulent, entitling Fullerton to punitive damages.

26 **THIRD CAUSE OF ACTION**
27 **(Negligence – Against All Defendants)**

28 405. Plaintiff realleges and incorporates herein by reference each and every allegation in

1 paragraphs 1 through 404 above as if set forth fully herein.

2 406. To establish actionable negligence in California, Plaintiff must show a duty, a breach
3 of that duty, and injury resulting proximately therefrom.

4 407. Defendants have a duty to exercise reasonable care under the circumstances, in light
5 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
6 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
7 and still have, a duty to exercise reasonable care to prevent the threatened harm.

8 408. In addition, Defendants had a duty not to breach the standard of care established
9 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
10 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
11 to abuse, and to develop and maintain systems to detect and report such activity.

12 409. Defendants voluntarily undertook a legal duty to prevent the diversion of
13 prescription opioids by engaging in the distribution of prescription opioids and by making public
14 promises to prevent the diversion of prescription opioids.

15 410. Defendants knew of the serious problem posed by prescription opioid diversion and
16 were under a legal obligation to take reasonable steps to prevent diversion.

17 411. Defendants knew of the highly addictive nature of prescription opioids and of the
18 high likelihood of foreseeable harm to patients and communities, including Fullerton, from
19 prescription opioid diversion.

20 412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
21 in accordance with applicable standards of conduct in advertising, marketing, selling, and
22 distributing opioid products in a safe manner to minimize the risk of addiction in patients and
23 resultant harm to those patients, their families and their communities, and to taxpayers and
24 municipal government such as Fullerton which must incur enormous expenditures for prevention,
25 treatment, emergency response and law enforcement costs and other foreseeable costs related to the
26 need to address the consequences of a large number of residents that become addicted to opioids as
27 a result of Defendants' conduct.

28 413. As described throughout the Complaint, Defendants breached their duties to

1 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
2 monitor for, failing to report, and filling highly suspicious orders time and again.

3 414. As described throughout the Complaint, in language expressly incorporated herein,
4 Defendants misrepresented their compliance with their duties under the law and concealed their
5 noncompliance and shipments of suspicious orders of opioids to Fullerton and destinations from
6 which they knew opioids were likely to be diverted into Fullerton, in addition to other
7 misrepresentations alleged and incorporated herein.

8 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
9 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
10 purported benefits of long-term use of opioids for the treatment of chronic pain.

11 416. Manufacturer Defendants knew or should have known, that their affirmative
12 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
13 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
14 representatives, and internal documents, should have put them on notice that such harm was not
15 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
16 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
17 and the public.

18 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
19 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

20 418. Defendants' misconduct alleged in this case is ongoing and persistent.

21 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
22 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
23 great probability of causing substantial harm.

24 420. As is described throughout this Complaint, Defendants acted without even slight
25 diligence or scant care, and with indifference, and were negligent in a very high degree,
26 disregarding the rights and safety of other persons, and said actions have a great probability of
27 causing substantial harm.

28 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*

(1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill in the in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and municipal government such as Fullerton, including, but not limited to, the following:

- a. Foreseeability of harm to Fullerton: Defendants were aware or reasonably should have been aware of the risk of addiction of a large number of patients in places such as Fullerton, and need for their care and treatment and in handling other consequences of their addiction and that such costs would be borne by local governments such as Fullerton;
- b. Degree of certainty Fullerton suffered harm: Fullerton has suffered enormous harm and costs in addressing treatment of addicted patients, including but not limited to expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences of a large number of residents that become addicted to opioids as a result of Defendants' conduct;
- c. Closeness of connection between Fullerton's harm: The explosion of opioid addiction and the presence of opioid addicted patients in Fullerton as a result of Defendants' conduct has resulted in expenditures directly for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences;
- d. Moral blame attached to Defendants' conduct: Defendants' knew or should have known that their wrongful conduct, actions and omissions would result in an explosion of patients who would become addicted to opioids, and that a vast opioid epidemic would result from the prescription of opioids to tens of millions

1 of patients nationwide, including within Fullerton, and that the costs would be
2 borne by the state, county and municipal local governments, while Defendants
3 profited tens of billions of dollars collectively from the widespread use of
4 prescription opioid products;

5
6 e. Policy of preventing future harm: As a direct and foreseeable result of
7 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
8 to occur on a vast scale both nationally and locally in places such as Fullerton
9 resulting in tremendous harm and cost to the patients, their families and the
10 communities in dealing with this epidemic and crisis, and there is a need to
11 ensure that the costs of such wrongful conduct is borne by Defendants so that
12 parties contemplating such or similar conduct in the future know they will be
13 held responsible for such harm;

14
15 f. Extent of burden to Defendants: There is no burden to Defendants in that state
16 and other law precludes them from engaging in the conduct alleged herein, and
17 there is no burden from precluding Defendants from profiting from their
18 wrongful conduct and operating within the confines of the law in advertising,
19 marketing, selling and distributing opioid products in a safe manner to minimize
20 the risk of addiction in patients and resultant harm to those patients, their
21 families and their communities, and to taxpayers and municipal government
22 such as Plaintiff Fullerton; and

23
24 g. Consequences to the community of imposing a duty to exercise care with
25 resulting liability for breach: Imposing a duty to not engage in Defendants'
26 wrongful conduct of advertising, marketing, selling and distributing opioid
27 products in an unsafe manner would minimize the risk of addiction in patients,
28

1 and liability for a breach of this duty would benefit communities such as
2 Fullerton in that they would not have to incur the foreseeable costs of the opioid
3 epidemic gripping the country and the nation.
4

5 422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled
6 substances laws cited above.

7 423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
8 and will continue to suffer economic damages including, but not limited to, significant expenses
9 for security services, emergency, health, prosecution, corrections, and rehabilitation services, as
10 well as the cost of opioid addiction treatment paid by Fullerton.

11 424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
12 and will continue to suffer stigma damage, non-physical property damage, and damage to its
13 proprietary interests.

14 425. Defendants' breaches of their duty of care foreseeably and proximately caused
15 damage to Fullerton and its residents.

16 426. Manufacturer Defendants are guilty of negligence per se in that the Defendants
17 violated applicable California laws, statutes, and regulations, in the manner in which they
18 advertised, marketed, sold and distributed opioid products.

19 427. Distributor Defendants are guilty of negligence per se in that the Defendants violated
20 California laws, statutes, and regulations designed to protect Plaintiff from the harms it has
21 suffered, including, but not limited to, the following:

- 22 a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug,
23 and Cosmetic Laws, California Health & Safety Code § 110390;
24 b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that
25 had been falsely advertised in violation of the Sherman Food, Drug, and
26 Cosmetic Laws, California Health & Safety Code § 110395;
27
28

- c. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;
- d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;
- e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and
- f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Fullerton. Fullerton, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Fullerton to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

430. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

1 431. As an expected and intended result of their conscious wrongdoing as set forth in this
2 Complaint, Defendants have profited and benefited from the increase in the distribution and
3 purchase of opioids within Fullerton, including from opioids foreseeably and deliberately diverted
4 within and into Fullerton.

5 432. Plaintiff has expended substantial amounts of money in an effort to remedy or
6 mitigate the societal harms caused by Defendants' conduct.

7 433. These expenditures include, but are not limited to, the provision of emergency
8 medical services and treatment services to people who use opioids.

9 434. These expenditures have helped sustain Defendants' businesses.

10 435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
11 externalities: the cost of the harms caused by Defendants' improper distribution practices.

12 436. Defendants were aware of these obvious benefits, and their retention of the benefit
13 is unjust.

14 437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
15 benefited from those payments because they allowed them to continue providing customers with a
16 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
17 Defendants obtained enrichment they would not otherwise have obtained. Because of their
18 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
19 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
20 lacks a remedy provided by law.

21 438. Defendants' misconduct alleged in this case is ongoing and persistent.

22 439. Defendants have unjustly retained benefits to the detriment of Fullerton, and
23 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
24 good conscience.

25 440. Fullerton is entitled to restitution and disgorgement from Defendants in an amount
26 to be determined at trial.

27 **FIFTH CAUSE OF ACTION**
28 **(Civil Conspiracy – Against All Defendants)**

1
2 441. Plaintiff realleges and incorporates herein by reference each and every allegation in
3 paragraphs 1 through 440 above as if set forth fully herein.

4 442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
5 and/or distribution of opioids into California and Fullerton.

6 443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
7 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
8 and Fullerton.

9 444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
10 report, and prevent suspicious orders of opioids.

11 445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
12 conspiracy by increasing the volume of opioid sales in the United States through creating a market
13 for non-medical use of opioids of epidemic proportions.

14 446. Many of the Manufacturing Defendants are members, participants, and/or sponsors
15 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
16 the HDA to give further assistance to the conspiracy.

17 447. The Manufacturing Defendants hid from the general public and suppressed and/or
18 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
19 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
20 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

21 448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
22 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
23 to commit acts of fraud.

24 449. Indeed, for the Defendants’ fraudulent scheme to work, each of the Defendants had
25 to agree to implement similar tactics.

26 450. By intentionally refusing to report and halt suspicious orders of their prescription
27 opioids, Defendants engaged in a fraudulent scheme.

28 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the

1 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
2 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
3 and were actually being diverted into the market of non-medical use.

4 452. Defendants further unlawfully marketed opioids in California and Fullerton in
5 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
6 dissemination of false and misleading information about the safety and efficacy of long-term opioid
7 use through, among other things: (a) the use of “Front Groups” that appeared to be independent of
8 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
9 continuing medical education (“CME”) programs controlled and/or funded by the Defendants; (d)
10 hiring and deploying so-called “key opinion leaders” or “KOLs” who were paid by the Defendants
11 to promote their message; and (e) the “detailing” activities of the Defendants’ sales forces, which
12 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
13 physicians lacking the expertise of pain care specialists.

14 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
15 unbiased, independent patient-advocacy and professional organizations in order to disseminate
16 patient education materials, a body of biased and unsupported scientific “literature,” and “treatment
17 guidelines” that promoted the Defendants’ false messages.

18 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
19 influence prescribers’ habits by promoting the Defendants’ false message through, among other
20 things, writing favorable journal articles and delivering supportive CMEs as if they were
21 independent medical professionals, thereby further obscuring the Defendants’ role in the
22 conspiracy.

23 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
24 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
25 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
26 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
27 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
28 were industry-friendly and would work together with the Defendants to advance the conspiracy.

1 456. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this
2 Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes.
3 Such allegations are specifically incorporated herein.

4 457. Defendants acted with a common understanding or design to commit unlawful acts,
5 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
6 proximately caused the injuries alleged herein.

7 458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
8 reasonable or lawful excuse.

9 459. Defendants conduct in furtherance of the conspiracy described herein was not mere
10 parallel conduct because each Defendant acted directly against their commercial interests in not
11 reporting the unlawful distribution practices of their competitors to the authorities, which they had
12 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
13 actual or tacit agreement between the Defendants that they would not report each other to the
14 authorities so they could all continue engaging in their unlawful conduct.

15 460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
16 thereof, caused the direct and foreseeable losses alleged herein.

17 461. Defendants' misconduct alleged in this case is ongoing and persistent.

18 462. As a result of Defendants' conspiracy, Fullerton is entitled to compensatory
19 damages in an amount to be proved at trial.

20 463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
21 fraudulent, entitling Fullerton to punitive damages.

22
23
24 **SIXTH CAUSE OF ACTION**
25 **(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

26 464. Plaintiff realleges and incorporates herein by reference each and every allegation in
27 paragraphs 1 through 463 above as if set forth fully herein.

28 465. California Business & Professions Code § 17500 makes it unlawful for a business

1 to make, disseminate, or cause to be made or disseminated to the public “any statement, concerning
2 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
3 exercise of reasonable care should be known, to be untrue or misleading.”

4 466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
5 designed to disseminate false or misleading statements designed to promote the belief that opioid
6 drugs could safely be used in a non-addictive manner.

7 467. By way of example, Actavis’s predecessor created a patient brochure for Kadian in
8 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome
9 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

10 468. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back
11 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
12 claimed that it is “less likely if you have never had an addiction problem.”

13 469. Cephalon and Purdue sponsored research and publications that falsely and
14 deceptively stated opioids did not have “ceiling dose.”

15 470. Purdue created websites, available to the public that instructed patients to seek new
16 medical providers out if their current provider would not increase their dose.

17 471. Defendants’ false and deceptive advertising practices resulted in increased opioid
18 dosages being prescribed to Fullerton’s residents, increasing the incidence of opioid addiction and
19 overdose in Fullerton.

20 472. Distributor Defendants also repeatedly omitted material information and/or falsely
21 represented that they were effectively preventing diversion and were monitoring, reporting, and
22 preventing suspicious orders.

23 473. As alleged above, Defendants’ statements about the risks associated with opioid use
24 were not supported by or were contrary to the scientific evidence.

25 474. As alleged above, each Defendant’s conduct, separately and collectively, was likely
26 to deceive California payors who purchased or covered the purchase of opioids.

27 475. Fullerton seeks restitution and injunctive relief under California Business &
28 Professions Code § 17535.

1 476. Fullerton also seeks an order assessing a civil penalty of two thousand five hundred
2 dollars (\$2,500) against Defendants for each violation of California's False Advertising Law
3 pursuant to California Business & Professions Code § 17536.

4 **SEVENTH CAUSE OF ACTION**
5 **(Negligent Failure to Warn— Against Manufacturer Defendants)**

6 477. Plaintiff realleges and incorporates herein by reference each and every allegation in
7 paragraphs 1 through 476 above as if set forth fully herein.

8 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
9 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
10 adequately warning the medical profession about the risk of addiction from the use of opioid
11 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
12 cancel out, and render meaningless any written warnings given about the risk of addiction from the
13 use of opioid products.

14 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
15 to adequately warn the medical profession about the risk of addiction from the use of opioid
16 products, including by overpromoting and over-marketing opioid products in a manner so as to
17 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
18 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
19 products in situations and for patients who should not have been using those drugs or should have
20 used them only as a last resort before other means were used or other less addictive and dangerous
21 drugs were prescribed.

22 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
23 and overpromoting and over-marketing the use of prescription opioid products, there is now a
24 national opioid addiction epidemic, including in Fullerton. The People, as a further direct and
25 proximate consequence and result thereof, sustained injuries and damages including but not limited
26 to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs,
27 law and regulatory enforcement costs, opioid disposal programs, and measures for prevention of
28 further opioid abuse and addiction.

1 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
2 fraudulent, entitling Fullerton to punitive damages.

3 **EIGHTH CAUSE OF ACTION**
4 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler Defendants)**

5 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
6 paragraphs 1 through 481 above as if set forth fully herein.

7 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
8 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
9 possess a right to payment from Purdue.

10 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
11 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
12 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
13 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

14 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
15 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
16 including Plaintiff.

17 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
18 them pursuant to California Civil Code § 3439.04(a)(1).

19 **NINTH CAUSE OF ACTION**
20 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

21 487. Plaintiff realleges and incorporates herein by reference each and every allegation in
22 paragraphs 1 through 486 above as if set forth fully herein.

23 488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
24 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
25 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
26 of its judgment against Purdue entered in this action.

27 489. After the Sackler Defendants became aware in or about 1999 that Purdue faced
28 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants

1 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping
2 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
3 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
4 Defendants and their extended family.

5 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
6 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
7 to commit acts of fraud.

8 491. Purdue and the Sackler Defendants acted with a common understanding or design
9 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
10 excuse, which directly and proximately caused the injuries alleged herein.

11 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
12 unlawfully, and without a reasonable or lawful excuse.

13 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
14 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
15 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
16 judgment entered in this action.

17 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
18 compensatory damages in an amount to be proved at trial.

19 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
20 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

21 22 **PRAYER FOR RELIEF**

23 WHEREFORE, Fullerton and the People respectfully request judgment in their favor
24 granting the following relief:

- 25 a) Entering Judgment in favor of Fullerton and the People in a final order against
- 26 each of the Defendants;
- 27 b) An award of actual and consequential damages in an amount to be determined at
- 28 trial;

- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff’s judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;

- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;
- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and
- v) Any other relief deemed just, proper, and/or equitable.

PLAINTIFFS DEMAND A JURY TRIAL ON ALL CLAIMS SO TRIABLE

ROBINS KAPLAN LLP

Dated: March 27, 2019

By: _____

Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT H

COPY

SUMMONS (CITACION JUDICIAL)

SUM-100

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment
 form is attached)

FOR COURT USE ONLY
 (SOLO PARA USO DE LA CORTE)

CONFORMED COPY
 ORIGINAL FILED
 Superior Court of California
 County of Los Angeles

MAR 28 2019

Sherri R. Carter, Executive Officer/Clerk of Court

By: Brigitte De La Rosa, Deputy

YOU ARE BEING SUED BY PLAINTIFF: CITY OF EL MONTE; and
(LO ESTÁ DEMANDANDO EL DEMANDANTE): THE PEOPLE OF THE
STATE OF CALIFORNIA, by and through El Monte City
Attorney Rick Olivarez

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **¡AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
 (El nombre y dirección de la corte es):

Los Angeles County Superior Court
 Stanley Mosk Courthouse
 111 North Hill Street
 Los Angeles, CA 90012

CASE NUMBER
 (Número del caso)

19STCV10532

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800
 Lucas A. Messenger, Bar No. 217645
 ROBINS KAPLAN LLP
 Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

SHERRI R. CARTER

Clerk, by

(Secretario)

Brigitte De La Rosa

Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

(SEAL)

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
 2. ☐ as the person sued under the fictitious name of (specify):

3. ☐ on behalf of (specify):

- under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other (specify):

4. ☐ by personal delivery on (date):

Page 1 of 1

SUM-200(A)

SHORT TITLE: City of El Monte, et al. v. Purdue Pharma
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY;
 THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

Page _____ of _____
 Page 1 of 1

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 Superior Court of California
 County of Los Angeles

MAR 28 2019

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(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF EL MONTE

CITY OF EL MONTE; and THE PEOPLE
 OF THE STATE OF CALIFORNIA, by
 and through El Monte City Attorney Rick
 Olivarez,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
 PHARMA INC.; THE PURDUE
 FREDERICK COMPANY; RICHARD S.
 SACKLER, an individual and as trustee for
 TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND
 SACKLER FAMILY; JONATHAN D.
 SACKLER, an individual and as trustee for
 TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND
 SACKLER FAMILY; MORTIMER D.A.
 SACKLER, an individual; KATHE A.

Case No. **19STCV10532**

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;
8. FRAUDULENT TRANSFER; and

ROBINS KAPLAN LLP
 ATTORNEYS AT LAW
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Attorneys for Plaintiffs City of El Monte and The
People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF EL MONTE

CITY OF EL MONTE; and THE PEOPLE
OF THE STATE OF CALIFORNIA, by
and through El Monte City Attorney Rick
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Plaintiffs,

v.

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PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
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MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

Case No.

PLAINTIFFS' COMPLAINT FOR:

- 1. PUBLIC NUISANCE;**
- 2. FRAUD;**
- 3. NEGLIGENCE;**
- 4. UNJUST ENRICHMENT;**
- 5. CIVIL CONSPIRACY;**
- 6. FALSE ADVERTISING;**
- 7. NEGLIGENT FAILURE TO WARN;**
- 8. FRAUDULENT TRANSFER; and**

1 SACKLER, an individual; IRENE
2 SACKLER LEFCOURT, an individual;
3 BEVERLY SACKLER, an individual and
4 as trustee for TRUST FOR THE BENEFIT
5 OF MEMBERS OF THE RAYMOND
6 SACKLER FAMILY; THERESA
7 SACKLER, an individual; DAVID A.
8 SACKLER, an individual; CEPHALON,
9 INC.; TEVA PHARMACEUTICAL
10 INDUSTRIES, LTD.; TEVA
11 PHARMACEUTICALS USA, INC.;
12 JANSSEN PHARMACEUTICALS, INC.;
13 JOHNSON & JOHNSON; ORTHO-
14 MCNEIL-JANSSEN
15 PHARMACEUTICALS, INC.; JANSSEN
16 PHARMACEUTICA, INC.; ENDO
HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS INC.; ACTAVIS
PLC; WATSON PHARMACEUTICALS,
INC.; WATSON LABORATORIES, INC.;
ACTAVIS PHARMA, INC.; ACTAVIS
LLC; ALLERGAN PLC; ALLERGAN,
INC.; ALLERGAN USA, INC.; INSYS
THERAPEUTICS, INC.;
MALLINCKRODT, PLC;
MALLINCKRODT, LLC; CARDINAL
HEALTH, INC.;
AMERISOURCEBERGEN
CORPORATION; MCKESSON
CORPORATION; and
DOES 1-100, inclusive,

Defendants.

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to El Monte Through Illicit Channels	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to El Monte Through Illicit Channels	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on El Monte.....	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff City of El Monte (hereinafter, “El Monte”) has been particularly hard hit, causing El Monte to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. El Monte, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California (the “People,” and together with El Monte, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants' efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. El Monte has seen increased costs of, among other things, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (e) public safety connected to the opioid epidemic within El Monte, including police, emergency

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 response services, and detention centers; (f) increased burden on El Monte's code enforcement
2 programs; (g) re-education of doctors and patients about the appropriate use of opioids; and (h)
3 extensive clean-up of public parks, spaces, and facilities. At the same time, El Monte has seen a
4 reduction to tax revenues caused by the epidemic created by the Defendants. Almost every citizen
5 of El Monte has been affected. The resulting damage to El Monte was directly and foreseeably
6 caused by Defendants' actions.

7 7. These increased costs could have been—and should have been—prevented by the
8 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
9 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
10 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
11 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
12 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
13 protecting opioids from theft, misuse, and diversion.

14 8. Instead of acting with reasonable care and in compliance with their legal duties,
15 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
16 process.

17 9. At the same time, Defendants flooded the market with false statements designed to
18 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
19 claims were false.³

20 10. Defendants' actions have not only caused significant costs, but have also created a
21 palpable climate of fear, distress, dysfunction and chaos among El Monte residents where opioid
22 diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

23 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
24 and/or unlawful conduct.

25
26
27
28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. El Monte, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. El Monte has standing to recover damage incurred because of Defendants' actions and omissions. El Monte has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical’s products and Janssen’s profits inure to J&J’s benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as “Actavis”).

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

1 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
2 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
3 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
4 California with the California Secretary of State.

5 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
6 principal place of business located in Chandler, Arizona.

7 38. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source
8 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
9 United States, including California. Subsys was indicated by the FDA for the treatment of
10 breakthrough cancer pain that other opioids could not eliminate.

11 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
12 bribe physicians with purported speaking fees for marketing and education events in exchange for
13 them prescribing Subsys for off-label uses. Insys’ founder and several other former Insys executives
14 were recently indicted by federal prosecutors on racketeering charges, alleging that these
15 individuals approved and fostered fraudulent behavior against insurance companies and also
16 conspired to bribe practitioners in various states. Insys Group is registered to do business in
17 California with the California Secretary of State.

18 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
19 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
20 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
21 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
22 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

23 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
24 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
25 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
26 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
27 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
28 Products are registered to do business in California with the California Secretary of State.

42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and Mallinckrodt are the “Manufacturer Defendants.”

C. The Distributor Defendants

43. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

44. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with El Monte and its residents, and has purposefully availed itself of the advantages of conducting business with and within El Monte. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

45. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

46. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with El Monte and its residents, and has purposefully availed itself of the advantages of conducting business with and within El Monte. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

48. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with El Monte and its residents, and has purposefully availed itself of the advantages of conducting business with and within El Monte. McKesson is in the chain of distribution of prescription opioids. McKesson

1 Corporation is registered to do business in California with the California Secretary of State.

2 49. The data which reveals and/or confirms the identity of the other wrongful opioid
3 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
4 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
5 voluntarily disclose the data necessary to identify with specificity the transactions which will form
6 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

7 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
8 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
9 listed on the New York Stock Exchange and their principal business consists of the nationwide
10 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
11 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
12 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
13 suspicious orders. El Monte has reason to believe each has engaged in unlawful conduct which
14 resulted in the distribution, dispensing, and diversion of prescription opioids into El Monte. El
15 Monte names each of the "Big 3" herein as defendants and places the industry on notice that El
16 Monte is acting to abate the public nuisance plaguing its community. Distributor Defendants have
17 had substantial contacts and business relationships with the People. Distributor Defendants have
18 purposefully availed themselves of business opportunities within El Monte.

19 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
20 Defendants."

21 **D. The Doe Defendants**

22 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
23 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
24 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
25 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff
26 is informed and believes, and on such information and belief alleges, that each of the Defendants
27 named as a DOE is responsible in some manner for the events and occurrences alleged in this
28 Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

53. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance in El Monte, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

54. Venue is proper in this Court because Defendants transact business in California and Los Angeles County, and some of the acts complained of occurred in this venue and the dispute arose in this venue.

IV. GENERAL FACTUAL ALLEGATIONS**A. An Overview of the Opioid Epidemic**

55. The term “opioid” includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: “Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, opioids can cause serious harm, including addiction, overdose, and death.”⁵

56. Prescription opioids with the highest potential for addiction are listed under Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such as codeine and morphine, also known generally as “opiates”), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

57. Historically, opioids were considered too addictive and debilitating for the treatment of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander, director of Johns Hopkins University’s Center for Drug Safety and Effectiveness, “[opioids] have very, very high inherent risks . . . and there’s no such thing as a fully safe opioid.”⁶

⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable->

58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

59. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

60. The market for chronic pain patients, however, was much larger, and to take advantage of it, the Defendants had to change doctors' general reluctance to prescribe opioids for chronic pain.⁷

61. As described herein, Defendants engaged in conduct that directly caused doctors to prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their obligations to prevent diversion of the highly addictive substance.

62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough for every person in the United States to have a bottle of pills. This represents an increase of 300% since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions were dispensed per 100 persons.

63. Many Americans, including Californians and residents of El Monte, are now addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United States, an increase of more than 22 percent over the previous year. The New York Times reported in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly

unproven-opioid-solution (last accessed December 20, 2017).

⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 2 a public health emergency by the President of the United States. The wave of opioid addiction was
 3 created by the increase in prescriptions.

4 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 5 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 6 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 7 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 8 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 9 80 percent of people who use heroin first misused prescription opioids.

10 65. Drug overdose deaths among all Americans increased more than 200 percent
 11 between 1999 and 2015.

12 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 13 there were 4,654 total opioid overdose deaths in 2016.⁹

14 ///

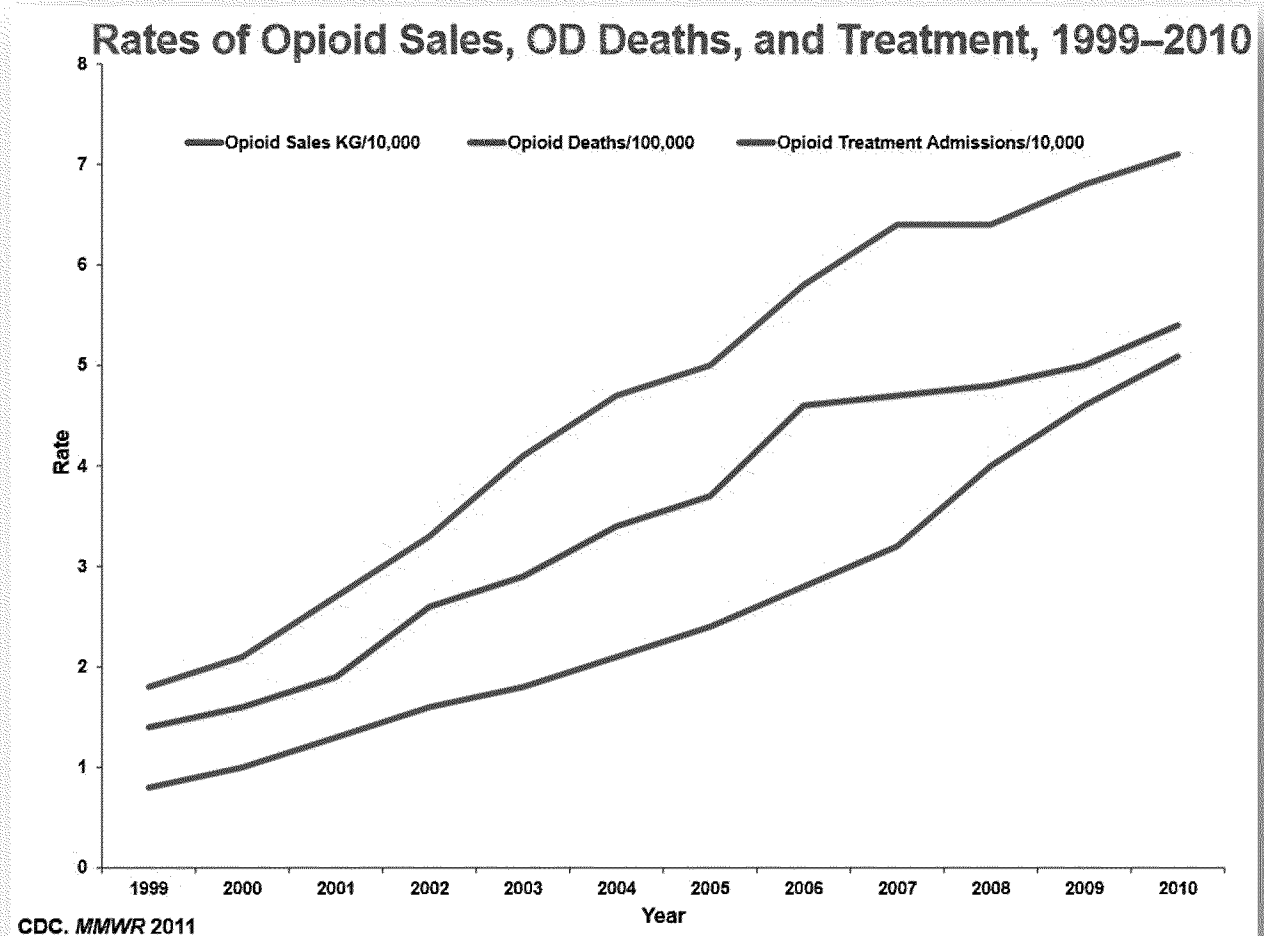
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26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*,” N.Y.
 27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, California Opioid Summary, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in El Monte, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that the Manufacturer Defendants’ messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
2 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
3 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
4 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
5 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
6 carried a low, or no, risk of addiction.

7 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
8 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
9 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
10 of actual addiction began appearing, and advocated that the signs of addiction should be treated
11 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
12 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
13 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
14 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
15 opioid use, including the supposed ability of opioids to improve function and quality of life, even
16 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
17 claims.

18 75. These statements were not only unsupported by or contrary to the scientific
19 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
20 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
21 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

22 76. The Manufacturer Defendants began their marketing schemes decades ago and
23 continue them today.

24 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
25 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
26 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
27
28

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 78. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 79. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 81. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 86. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 87. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 89. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 90. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 91. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 94. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 97. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 98. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and

24 _____
 25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 29, 2017).

27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 100. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
6 unbranded advertising stated that “People who take opioids as prescribed usually do not become
7 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use.”

10 101. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 104. For example, the New York Attorney General (“NY AG”) found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 106. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 108. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in El Monte and doctors treating residents of El Monte.²⁰

12 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 113. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 114. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 115. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 _____
28 ²³ Dr. Portenoy was a member of the board of the APF.

²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 118. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 119. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 120. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 121. On information and belief, AAPM is viewed internally by Endo as “industry

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26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 122. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

26
27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in El Monte during the relevant time period, are still available online, and were often
 12 reprinted in the Journal of Pain, which is the official journal of the American Pain Society. The
 13 Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 126. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 128. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 129. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 130. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 131. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
25 marketing materials along with the rights to Kadian, it appears that Actavis
26 continued to use this brochure in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
28 People Living with Pain (2007), which suggests that addiction is rare and
limited to extreme cases of unauthorized dose escalations, obtaining
duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in El Monte, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 138. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain is *under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in El Monte, to PartnersAgainstPain.com, which contained false and
14 misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 **Deceptive Claims of Pseudoaddiction**

22 139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
some of its proponents” and reported that despite the fact that Endo trained its sales representative
to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
Management testified to [the NY AG] that he was not aware of any research validating the
‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 141. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including El Monte the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

142. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse—“for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that available risk screening tools “show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

143. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

144. For example, on information and belief, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.³⁸ This publication was available on APF’s website until the organization dissolved in May 2012.

146. Detailers for Janssen have told and continue to tell doctors in California, including El Monte, that their patients would not experience withdrawal if they stopped using opioids.

Deceptive Minimization of Opioid Withdrawal

147. The Manufacturer Defendants also deceptively minimized the significant symptoms of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly understated the difficulty of tapering, particularly after long-term opioid use.

148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected physiologic response in patients exposed to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that “more than a few days of exposure to opioids significantly increases hazards” and “each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence” and highlights the difficulties, including the need to carefully identify “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk

149. The Manufacturer Defendants also falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants, are described below:

- a. On information and belief, Actavis’s predecessor created a patient brochure for Kadian in 2007 that stated, “Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction.” Upon information and belief, based on Actavis’ acquisition of its predecessor’s marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients “need” a larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in El Monte that they should increase the dose of OxyContin, rather
than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 154. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Opana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was **no** evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in El Monte, that Opana ER is harder to abuse and given demonstrations to nurse
22 practitioners about Opana ER’s purported abuse deterrent properties.

23
24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
[push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
[ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

1 157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements
2 in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those
3 statements to be false and misleading because there was no difference in the ability to extract the
4 narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge
5 of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy
6 benefit managers.

7 158. Because Orpana ER could be “readily prepared for injection” and was linked to
8 outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that
9 Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on
10 June 8, 2017, and requested that Endo withdraw Opana ER from the market.

11 159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of
12 its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not
13 market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and
14 believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-
15 called abuse deterrent properties of Purdue’s opioid products as a primary selling point to
16 differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim
17 that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim
18 that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to
19 yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids
20 are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral
21 abuse or misuse, and that its abuse deterrent properties can be defeated.

22 160. These statements and omissions by Purdue are false and misleading, and conflict
23 with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates
24 that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent
25 properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent
26 properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD
27 opioids prevent or reduce abuse, misuse, or diversion.

28 161. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 163. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 164. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 27 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 28 430.

⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose
 epidemic*, Business Insider (Mar. 14, 2016), available at [http://www.businessinsider.com/robert-califf-
 abuse-deterrent-drugs-have-a-big-flaw-2016-3](http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3) (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 165. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 166. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

170. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in El Monte, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

172. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewharper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

174. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

26 _____
27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 182. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 186. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 187. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by El Monte.

18 191. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

26
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

28 ⁵² *Id.*

misrepresentations deceived and continue to deceive doctors and patients in California, including in El Monte, about the risks and benefits of long-term opioid use. California doctors confirm this. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. Plaintiff is informed and believes that California residents were never told that they might become addicted to opioids when they started taking them, were told that they could easily stop using opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

192. Numerous doctors and substance abuse counselors in California note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic. Treatment centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients for opioid addiction.

193. The Manufacturer Defendants knew and should have known that their misrepresentations about the risks and benefits of long-term opioid use were false and misleading when they made them.

194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids caused and continue to cause doctors in California, including doctors in El Monte, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia, rather than prescribing less addictive medications. Absent Manufacturers Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids to as many patients, and there would not have been as many opioids available for misuse and abuse or as much demand for those opioids.

195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of their opioids have caused and continue to cause the prescribing and use of opioids to explode in California, including in El Monte. Opioids are the most common means of treatment for chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per

1 year are prescribed a long-acting opioid.

2 196. In California, including El Monte, Manufacturer Defendants' deceptive marketing
3 of the abuse-deterrent properties of their opioids during the past few years has been particularly
4 effective. For example, one survey reports that pain specialists were more likely to recognize that
5 OxyContin had abuse deterrent properties and to prescribe OxyContin specifically because of those
6 properties. Further, prescribers who knew of OxyContin's abuse deterrent properties were using
7 more of it than those who did not know it was an AD opioid. Although sales of AD opioids still
8 represent only a small fraction of opioids sold (less than 5% of all opioids sold in 2015), they
9 represent a disproportionate share of opioid sales revenue (\$2.4 billion or approximately 25% in
10 opioid sales revenue in 2015).

11 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 198. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 199. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 200. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 201. Diversion can occur at any point in the opioid supply chain.

4 202. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 205. Opioid diversion occurs at an alarming rate in the United States.

23 206. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 **210.** In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 211. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 212. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for El Monte and the people therein.

25 213. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

1 214. Thus, all opioid distributors are required to maintain effective controls against
2 opioid diversion. They are required to create and use a system to identify and report to the California
3 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
4 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
5 and/or orders of unusual frequency. To comply with these requirements, distributors must know
6 their customers, must conduct due diligence, must report suspicious orders, and must terminate
7 orders if there are indications of diversion.

8 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
9 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
10 their obligations under the CSA.

11 216. Under the CSA, anyone authorized to handle controlled substances must track
12 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
13 automated drug reporting system that records and monitors the flow of Schedule II controlled
14 substances from the point of manufacture through distribution to the point of sale. ARCOS
15 accumulates data on distributors' controlled substances and transactions, which are then used to
16 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
17 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
18 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
19 and current record of each substance manufactured, imported, received, sold, delivered, exported,
20 or otherwise disposed of.

21 217. Plaintiff does not bring causes of action based on violations of federal statutes and
22 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
23 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
24 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
25 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
26 prescription opioids.

1 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
 2 **Opioids to El Monte Through Illicit Channels**

3 218. The Distributor Defendants have been and continue to be well-aware of problems
 4 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance
 5 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
 6 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
 7 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
 8 that the DEA also provides distributors with data on controlled substance distribution patterns and
 9 trends, including data on the volume and frequency of orders and the percentage of controlled
 10 versus non-controlled purchases. The distributors are also given case studies, legal findings against
 11 other registrants, and ARCOS profiles of their customers whose previous purchases may have
 12 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
 13 Defendants should look for in order to identify potential diversion.

14 219. Since 2007, the DEA has hosted at least five conferences to provide registrants with
 15 updated information about diversion trends and regulatory changes that affect the drug supply
 16 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
 17 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
 18 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
 19 also request clarification on DEA policies, procedures, and interpretations of the CSA and
 20 implementing regulations.

21 220. Since 2008, the DEA also has participated in numerous meetings and events with
 22 the legacy Healthcare Distribution Management Association (HDMA), now known as the
 23 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
 24 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
 25 guidance to the association concerning suspicious order monitoring, and the association has
 26 published guidance documents for its members on suspicious order monitoring, reporting
 27 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
 28 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 223. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 224. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 225. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 226. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

229. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 230. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to El
6 Monte and its residents. Each Distributor Defendant knew or should have known that the opioids
7 reaching El Monte were not being consumed for medical purposes and that the amount of opioids
8 flowing to El Monte was far in excess of what could be consumed for medically necessary purposes.

9 232. The Distributor Defendants negligently or intentionally failed to adequately control
10 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
11 substances would have anticipated the danger of opioid diversion and protected against it by, for
12 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
13 greater oversight, security, and control of supply channels; (c) looking more closely at the
14 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
15 amounts greater than the populations in those areas would warrant; (d) investigating demographic
16 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
17 El Monte; (e) providing information to pharmacies and retailers about opioid diversion; and (f) in
18 general, simply following applicable statutes, regulations, professional standards, and guidance
19 from government agencies and using a little bit of common sense.

20 233. On information and belief, the Distributor Defendants made little to no effort to visit
21 the pharmacies servicing the areas around El Monte to perform due diligence inspections to ensure
22 that the controlled substances the Distributor Defendants had furnished were not being diverted to
23 illegal uses.

24 234. On information and belief, the compensation the Distributor Defendants provided
25 to certain of their employees was affected, in part, by the volume of their sales of opioids to
26 pharmacies and other facilities servicing the areas around El Monte, thus improperly creating
27 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid
28 abuse.

1 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
2 flooding the market in and around El Monte with highly addictive opioids would allow opioids to
3 fall into the hands of children, addicts, criminals, and other unintended users.

4 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
5 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
6 and death. It was also reasonably foreseeable that many of these injuries would be suffered by El
7 Monte residents, and that the costs of these injuries would be borne by El Monte.

8 237. The Distributor Defendants knew or should have known that the opioids being
9 diverted from their supply chains would contribute to the opioid epidemic faced by El Monte, and
10 would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
11 addiction, demand, illegal transactions, economic ruin, and human tragedy.

12 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
13 and around El Monte, but, on information and belief, they nevertheless persisted in a pattern of
14 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
15 with such frequency that they knew or should have known these commonly abused controlled
16 substances were not being prescribed and consumed for legitimate medical purposes.

17 239. The use of opioids by El Monte residents who were addicted or who did not have a
18 medically necessary purpose could not have occurred without the knowing cooperation, assistance,
19 or negligent failure to act of and by the Distributor Defendants. If the Distributor Defendants
20 adhered to effective controls to guard against diversion, El Monte and its residents would have
21 avoided significant injury.

22 240. The Distributor Defendants made substantial profits over the years based on the
23 diversion of opioids into El Monte. The Distributor Defendants knew that El Monte would be
24 unjustly forced to bear the costs of these injuries and damages.

25 241. The Distributor Defendants' intentional distribution of excessive amounts of
26 prescription opioids showed an intentional or reckless disregard for the safety of El Monte and its
27 residents. Their conduct poses a continuing threat to the health, safety, and welfare of El Monte.

28 242. The state laws at issue here are public safety laws.

1 243. The Distributor Defendants' violations constitute prima facie evidence of
2 negligence under state law.

3 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
4 **of Opioids to El Monte Through Illicit Channels**

5 244. The same legal duties to prevent diversion, and to monitor, report, and prevent
6 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
7 were also legally required of the Manufacturer Defendants under California law.

8 245. In addition to a common law duty to exercise reasonable care in the promotion and
9 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
10 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
11 determined by the Board. *See* 16 CCR 1782.

12 246. On information and belief, for over a decade the Manufacturer Defendants have
13 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
14 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
15 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
16 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
17 Manufacturer Defendants breached their duties under state law.

18 247. The Manufacturer Defendants had access to and possession of the information
19 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
20 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
21 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
22 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
23 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
24 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
25 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
26 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer
27 Defendants built receipt of this information into the payment structure for the opioids provided to
28 the opioid distributors.

248. The Manufacturer Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into El Monte.

F. The Defendants Knowingly Profit from an Interstate Opioid Crisis

249. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state, city, and county lines in a variety of ways.

250. First, prescriptions written in one state would, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another.

251. When authorities in one state cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of regulatory oversight created a fertile ground for pill mills. Residents of many states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

252. The facts surrounding numerous criminal prosecutions illustrate this common practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught flying to California in attempts to obtain additional sources of supply for their drug operation which consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

253. In another example, a man from Warren County, Ohio, who was sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone

⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

⁵⁹ Andrew Welsh-Huggins, Associated Press, 'Prescription Tourists' Thwart States' Crackdown on Illegal Sale of Painkillers, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

1 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
2 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
3 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
4 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
5 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

6 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
7 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
8 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
9 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
10 customers were from other states.⁶³

11 255. In yet another case, defendants who operated a pill mill in south Florida within
12 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
13 transported oxycodone back to the area for both use and distribution by local drug trafficking
14 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
15 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
16 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
17 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
18 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
19 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
20

21 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
22 <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
accessed July 25, 2018).

23 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
24 [sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

25 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
<https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
26 accessed July 25, 2018).

27 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
[https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
28 [patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

1 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
2 Kentucky residents.”⁶⁵

3 256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
4 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
5 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
6 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
7 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
8 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
9 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
10 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
11 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

12 257. While the I-75 corridor was well utilized, prescription tourists also came from other
13 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
14 mills come from as far away as Arizona and Nebraska.⁷⁰

15 258. Similar pipelines developed in other regions of the country. For example, the I-95
16 corridor was another transport route for prescription pills. As the director of the Maine Drug
17 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
18 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
19 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
20 Ohio, and Kentucky.

21 _____
22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s*
24 *Deadliest Drug Epidemic* 171 (2016).

25 ⁶⁷ *Id.* at 172

26 ⁶⁸ *Id.* at 171

27 ⁶⁹ *Id.*

28 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
(last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
(last accessed July 25, 2018)

259. Along the west coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷² Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.

260. Defendants certainly were aware, or should have been aware, that pill mills from around the country were pushing its products. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from data vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The data vendors' information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.

261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.

262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,

⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

⁷³ *Id.*

1 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
2 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
3 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

4 ⁷⁴

5 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
6 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
7 sales representative "it was packed with a line out the door, with people who looked like gang
8 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
9 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
10 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
11 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
12 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
13 2010 to inform the authorities.

14 264. Abundant evidence, thus, establishes that prescription opioids migrated between
15 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
16 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
17 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
18 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
19 prescription opioid pills were hard to get in one area, they migrated from another. The
20 manufacturers and distributors were fully aware of this phenomenon and profited from it.

21 265. Defendants each knew or should have known that opioid diversion and abuse was
22 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide
23 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
24 allowed to continue the unlawful diversion of opioids into El Monte.

25 _____
26 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages

266. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and the sale of their products, as well as the rates of opioid-related substance abuse, hospitalization, and death among El Monte residents and across the nation. Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of opioids into communities like El Monte, fueling the epidemic.

267. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."⁷⁷

268. Opioids are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

269. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."⁷⁹

270. The increased abuse of prescription opioids—along with growing sales—has contributed to a large number of overdoses and deaths.

271. As shown above, the opioid epidemic has escalated in El Monte with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants' increased distribution of opioids.

272. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to El Monte and areas from which opioids are being diverted to El Monte, has caused the opioid epidemic to include heroin addiction, abuse, and death.

273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in El Monte.

⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in El Monte.

275. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in El Monte.

276. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in El Monte. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by El Monte and residents of El Monte.

277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which El Monte seeks relief, as alleged herein. El Monte also seeks the means to abate the epidemic created by the Defendants.

278. El Monte seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

279. El Monte seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

280. El Monte seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

281. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

282. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

283. The community-based problems require community-based solutions that have been

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed January 8, 2018).

1 limited by budgetary constraints.

2 284. Having profited enormously through the aggressive sale, misleading promotion, and
3 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
4 financial burdens their conduct has inflicted upon El Monte.

5 285. The opioid epidemic still rages because the fines and suspensions imposed by the
6 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
7 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
8 registration numbers and when one facility is suspended, they simply ship from another facility.

9 286. The Defendants have abandoned their duties imposed by the law, taken advantage
10 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in El
11 Monte.

12 287. In the course of conduct described in this Complaint, Defendants have acted with
13 oppression, fraud, and malice, both actual and presumed.

14 **H. The Impact of Opioid Abuse on El Monte**

15 288. Defendants' creation, through false and misleading advertising and a failure to
16 prevent diversion, of a virtually limitless opioid market has significantly harmed El Monte and
17 resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
18 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
19 abused come, directly or indirectly, through doctors' prescriptions.

20 289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
21 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
22 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
23 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
24 associated with the consumption of a counterfeit version of the prescription drug Norco
25 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has
26 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
27 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
28 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further

1 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
2 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
3 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
4 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
5 related overdoses, with 55% of those resulting from prescription opioids.

6 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
7 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
8 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
9 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
10 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

11 291. Even El Monte's youngest residents bear the consequences of the opioid abuse
12 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
13 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
14 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
15 Many El Monte women have become addicted to prescription opioids and have used these drugs
16 during their pregnancies. As a result, many El Monte infants suffer from opioid withdrawal and
17 Neonatal Abstinence Syndrome ("NAS").⁸⁵

18 292. The impact of NAS can be life-long. Most NAS infants are immediately transferred
19 to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require
20

21 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
22 *year*, LA Times (Oct. 27, 2014), available at [http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html)
[prescription-hospital-er-20141026-story.html](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html) (last accessed December 21, 2017).

23 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
24 *The Opioid Crisis in Indian Country*, at 37, available at
<https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
25 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US., 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

26 ⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
27 Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
28 21, 2017).

⁸⁵ Jean Y, Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at
<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 an emergency evacuation for care to save the infant's life. Such emergency transportation can cost
2 thousands of dollars for each occurrence.

3 293. Many NAS infants have short-term and long-term developmental issues that prevent
4 them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and
5 digestive issues; some are unable to attend full days of school. These disabilities follow these
6 children through elementary school and beyond.

7 294. Many of the parents of these children continue to relapse into prescription opioid
8 use and abuse. As a result, many of these children are placed in foster care or adopted.

9 295. Opioid addiction is now the primary reason that Californians seek substance abuse
10 treatment, and admissions to drug treatment facilities in California more than doubled from
11 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one
12 facility in northern California, up to 90% – started on legal opioid prescriptions.

13 296. The explosion in opioid prescriptions and use caused by Defendants has led to a
14 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
15 overdoses and deaths as well as devastating social and economic consequences. This public health
16 crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable
17 enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]”
18 and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each
19 Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting
20 worse.

21 297. There is little doubt that each Defendant's deceptive marketing and distribution
22 scheme has precipitated this public health crisis in California, including El Monte, by dramatically
23 increasing opioid prescriptions and use. An oversupply of prescription opioids has provided a
24 source for illicit use or sale of opioids (the supply), while the widespread use of opioids has created
25 a population of patients physically and psychologically dependent on them (the demand). And when
26 those patients can no longer afford or legitimately obtain opioids, they often turn to the street to
27 buy prescription opioids or even heroin.

28 298. The effects of Defendants' deceptive marketing and distribution scheme has further

1 impacted Plaintiff in a foreseeable way such that El Monte must devote increased resources to the
 2 burden of the addicted homeless who commit drug and property crimes, to feed their addiction. For
 3 example, tax dollars are required to maintain public safety of places where the addicted homeless
 4 attempt to congregate, including parks, schools and public lands. Tax dollars are required to fight
 5 the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
 6 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
 7 *aureus* (MRSA) are spread by opioid abuse.

8 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
 9 have recruited addicts nationally with false and misleading promises of the medically supervised
 10 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
 11 effective rehabilitation available in beautiful California communities. These for-profit
 12 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
 13 that many have provided substandard care including use of physicians who have had their license
 14 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
 15 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
 16 as long as there are third party payments available, and then throw them out of the facilities to be
 17 homeless. These addicts brought to California by the substandard rehab industry, have further
 18 contributed to the public's burden by discharging addicted homeless into the community who
 19 require further care and rehabilitation at the public's expense, and who commit crimes in California
 20 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
 21 all relevant times when they deceptively marketed their products as non-addictive that such
 22 addiction would be highly difficult to overcome. Defendants knew or should have known that
 23 municipalities, including El Monte, would bear the burden of costs associated with rehabilitation
 24 business of all types.

25 300. The role of Defendants' deceptive marketing and distribution scheme in causing this
 26 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
 27 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
 28 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have

1 contributed to the severity of the current prescription drug abuse problem.” And in August 2016,
 2 the former U.S. Surgeon General expressly connected the “urgent health crisis” to “heavy
 3 marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that opioids
 4 are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment
 5 specialists, and law enforcement and public health officials confirm that prescription opioids
 6 lawfully prescribed by doctors have fueled this epidemic.

7 301. Absent each Defendant’s deceptive marketing scheme and improper distribution,
 8 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
 9 the opioid epidemic that now exists would have been averted or much less severe.

10 302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
 11 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
 12 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
 13 only engaged in false advertising, they have also created or assisted in the creation of a public
 14 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the
 15 present is part of its deceptive marketing and distribution scheme and subjects that Defendant to
 16 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
 17 *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual
 18 obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance
 19 of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

20 303. Accordingly, Defendants’ conduct, both individually and collectively, has violated
 21 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
 22 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. El Monte does not seek to limit the
 23 ability of doctors in California to prescribe opioids. El Monte does not ask this Court to weigh the
 24 risks and benefits of long-term opioid use. Instead, El Monte seeks an order requiring Defendants
 25 to cease their unlawful promotion and distribution of opioids, to correct their misrepresentations,
 26 and to abate the public nuisance they have created. To redress and punish Defendants’ previous and
 27 current violations of law that cause and continue to cause harm to El Monte, Plaintiff seeks a
 28 judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law.

1 304. By this action, El Monte further seeks to recoup tax dollars spent already for the
2 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
3 impact on this county and its communities, and to abate the opioid nuisance so El Monte will not
4 be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
5 wrongful conduct as alleged herein.

6 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
7 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
8 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
9 California spiked by 34% from 2011 to 2013.

10 306. Opioid abuse also contributes to a range of social problems including physical and
11 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
12 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
13 unemployment, and despair. More and more El Monte resources are needed to combat these
14 problems. The prescription opioid crisis also diminishes El Monte's available workforce, decreases
15 productivity, increases poverty, and requires greater governmental expenditures by El Monte.

16 307. The prescription opioid crisis has directly financially injured El Monte. The crisis
17 has led to an increased demand for, *inter alia*, security services (such as police, EMS, detention),
18 child protective services, health services, clean-up services, and legal services. El Monte has also
19 had to hire additional staff and expend additional resources to manage the demand.

20 308. El Monte's medical services have seen an increase in opioid-related health problems
21 among El Monte residents, including, but not limited to, infants born with opioid-related medical
22 conditions. This has resulted in increased demand and increased expenses.

23 309. El Monte has also suffered substantial financial damages in the form of lost
24 productivity of El Monte employees and residents, lost economic activity, lost reputation and good
25 will, and the lost opportunity for growth. These damages have been suffered and continue to be
26 suffered directly by El Monte.

27 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
28 their homes and their families. Some will get treatment and fewer will successfully complete it;

1 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
 2 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
 3 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
 4 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
 5 drug transactions; or dying from opioid-induced heart or neurological disease.

6 311. El Monte also has suffered substantial financial damages in the form of lost taxes
 7 paid by its residents and businesses as a result of lost earnings and productivity.

8 312. While the use of opioids has taken an enormous toll on El Monte and its residents,
 9 Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in
 10 revenue for drug companies like the Defendants. Indeed, on information and belief, each Defendant
 11 experienced a material increase in sales, revenue, and profits from the unlawful conduct described
 12 above.

13 **I. The Statutes of Limitations Are Tolloed and Defendants Are Estopped from**
 14 **Asserting Statutes of Limitations As Defenses**

15 313. Defendants' conduct has continued from the early 1990s through today and remains
 16 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
 17 continuous injury. The damages have not occurred all at once but have continued to occur and have
 18 increased as time progresses. The tort is not completed nor have all the damages been incurred until
 19 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
 20 public nuisance remains unabated.

21 314. Defendants are equitably estopped from relying upon a statute of limitations defense
 22 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
 23 assure the public that they were undertaking efforts to comply with their obligations under the
 24 controlled substances laws, all with the goal of continuing to generate profits.

25 315. For example, a Cardinal Health executive claimed that it uses "advanced analytics"
 26 to monitor its supply chain, and assured the public it was being "as effective and efficient as
 27
 28

possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”⁸⁷

317. Defendants, through their trade associations, filed an amicus brief that represented that Defendants took their duties seriously, complied with their statutory and regulatory responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

318. Defendants purposely concealed their wrongful conduct, including by assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their behavior by providing the public with false information about opioids and have continued to use Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct is continuing to this day.

319. Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which will confirm their identities and the extent of their wrongful and illegal activities.

320. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a distributor’s license was raised.

⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html (last accessed December 21, 2017)

⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, (Dec. 22, 2016), available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed December 21, 2017).

⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4, 2016).

⁸⁹ See Higham and Bernstein, *supra* note 53.

1 321. In addition, the Defendants fraudulently attempted to convince the public that they
2 were complying with their legal obligations and working to curb the opioid epidemic.

3 322. Because the Defendants concealed the facts surrounding the opioid epidemic, El
4 Monte did not know if the existence or scope of the Defendants' misconduct, and could not have
5 acquired such knowledge earlier through the exercise of reasonable diligence.

6 323. Defendants intended that their false statements and omissions be relied upon,
7 including by El Monte, and its residents.

8 324. Defendants knew of their wrongful acts and had material information pertinent to
9 their discovery, but concealed that information from the public, including El Monte, and its
10 residents. Only Defendants knew of their widespread misinformation campaign and of their
11 repeated, intentional failures to prevent opioid diversion.

12 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
13 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
14 opioid crisis have only recently come to light.

15 326. Defendants had actual knowledge that their conduct was deceptive, and they
16 intended it to be deceptive.

17 327. El Monte was unable to obtain vital information regarding these claims absent any
18 fault or lack of diligence on El Monte's part.

19 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

20 **A. The Marketing Scheme**

21 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
22 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
23 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
24 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
25 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
26 long-term, chronic pain. Through their personal relationships, the members of this marketing
27 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
28 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the

1 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

2 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
3 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
4 made misleading statements and misrepresentations about opioids that downplayed the risk of
5 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
6 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
7 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
8 of an invented condition the Manufacturer Defendants named “pseudoaddiction”; (d) withdrawal
9 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
10 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
11 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
12 formulations provide a solution to opioid abuse.

13 330. The marketing scheme devised, implemented and conducted by the Manufacturer
14 Defendants was designed to ensure that they unlawfully increased their sales and profits through
15 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
16 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
17 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
18 network as described above.

19 331. There was regular communication between the Manufacturer Defendants, Front
20 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
21 exchanged. Typically, the coordination, communication and payment occurred, and continues to
22 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
23 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
24 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
25 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
26 each agreed and took actions to hide the scheme and continue its existence.

27 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants’
28 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front

1 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
2 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
3 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
4 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
5 their members and constituents. By failing to disclose this information, Front Groups perpetuated
6 the marketing scheme, and reaped substantial benefits.

7 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
8 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
9 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
10 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
11 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
12 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
13 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
14 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
15 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
16 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
17 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
18 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

19 334. As public scrutiny and media coverage focused on how opioids ravaged
20 communities in California and throughout the United States, the Front Groups and KOLS did not
21 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
22 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
23 using opioids for chronic pain.

24 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
25 categories of activities in furtherance of the marketing scheme. As described herein, the
26 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
27 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
28 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to

1 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
2 and (d) efforts to limit prescriber accountability.

3 336. In addition to disseminating misrepresentations about the risks and benefits of
4 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
5 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
6 criticized or undermined the CDC Guidelines which represented “an important step – and perhaps
7 the first major step from the federal government - toward limiting opioid prescriptions for chronic
8 pain.”

9 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
10 the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not
11 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
12 of the individuals who participated in the construction of these guidelines.”

13 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
14 president, stating “that the CDC guideline makes disproportionately strong recommendations based
15 upon a narrowly selected portion of the available clinical evidence.”

16 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
17 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
18 “neutral” and more “scientific” than the Manufacturer Defendants themselves. Without the work
19 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
20 scheme could not have achieved its common purpose.

21 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to
22 be prescribed and used for chronic pain throughout El Monte, and the epidemic continues to injure
23 Plaintiff, and consume the resources of Plaintiff’s emergency health services and law enforcement
24 systems.

25 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
26 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
27 in the object of the scheme, and functioned within a structure designed to effectuate the scheme’s
28 purpose.

B. The Distribution Scheme

342. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to “a categorical denial of any criminal behavior or intent.”⁹⁰ Defendants’ actions went far beyond what could be considered ordinary business conduct. For more than a decade, the Distributor Defendants worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

343. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, California enacted California Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems to detect and report such activity.

344. If morality and the law did not suffice, competition dictates that the Distributor Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so.

345. The Distributor Defendants’ scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for state authorities or the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the

⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, the Distributor Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

346. As described above, at all relevant times, the Distributor Defendants conspired together for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

347. At all relevant times, as described above, the Distributor Defendants exerted control over, conducted and/or participated in distribution scheme by fraudulently claiming that they were complying with their duties under California law to report suspicious orders and to maintain systems to detect and report such activity.

348. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators’ ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁹¹

⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at <https://www.w>

349. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

350. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

351. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

352. Each Defendant's conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under California Business & Professions Code § 17536.

353. As a members of the boards of various Purdue entities, the Sacklers oversaw all

[washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html) (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 aspects of Purdue's marketing and promotion of opioid products. As board members who were
2 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
3 known, of Purdue's deceptive marketing tactics of opioid products.

4 354. The Sackler Defendants also were aware of specific examples of deceptive
5 marketing through receipt of call note reviews in their capacities as board members. On information
6 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
7 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
8 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

9 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
10 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
11 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
12 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

13 356. By 2006, prosecutors at the United States Department of Justice found damning
14 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
15 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
16 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
17 events and side effects than other pain medications.

18 357. As members of the family that owns Purdue, the Sackler Defendants personally
19 benefitted from the success of OxyContin. At various points, as directors, they approved the
20 distribution of funds from Purdue to shareholders, including themselves and their extended family.

21 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
22 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
23 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
24 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
25 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
26 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
27 the opioid related liabilities of the companies from which they were transferred.

28 359. Plaintiff is informed and believes that due to the billions of dollars in profits that

1 have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to
 2 satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced
 3 litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the
 4 Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly
 5 profited and received the benefits of that wrongdoing.

6 VII. CAUSES OF ACTION

7 FIRST CAUSE OF ACTION

8 (Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)

9 360. Plaintiff realleges and incorporates herein by reference each and every allegation in
 10 paragraphs 1 through 359 above as if set forth fully herein.

11 361. California Civil Code § 3479 provides that “anything which is injurious to health ...
 12 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
 13 interfere with the comfortable enjoyment of life or property ... is a nuisance.”

14 362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at
 15 the same time an entire community or neighborhood, or any considerable number of persons,
 16 although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

17 363. California Civil Code § 3490 states that “no lapse of time can legalize a public
 18 nuisance, amounting to an actual obstruction of public right.”

19 364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought
 20 by El Monte to abate the public nuisance created by the Defendants.

21 365. Each Defendant, acting individually and in concert, has created or assisted in the
 22 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment
 23 of life and property of entire communities or neighborhoods or of any considerable number of
 24 persons in El Monte in violation of California Civil Code §§ 3479 and 3480.

25 366. The public nuisance is substantial and unreasonable. Defendants’ actions caused and
 26 continue to cause the public health epidemic described above in El Monte, and that harm outweighs
 27 any offsetting benefit.

28 367. Defendants knew and should have known that their promotion and distribution of

1 opioids was false and misleading and that their deceptive marketing scheme would create or assist
2 in the creation of the public nuisance—i.e., the opioid epidemic.

3 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
4 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
5 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
6 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
7 so widespread, and the opioid epidemic that now exists would have been averted or much less
8 severe.

9 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
10 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
11 can be abated.

12 370. Each Defendant is liable for public nuisance because its conduct at issue is
13 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
14 endangers the safety, health, morals, comfort, or repose of a considerable number of people in El
15 Monte. Defendants' conduct is also indecent or offensive to the senses, and constitutes an
16 obstruction to the free use of property sufficient to constitute an interference with the people of El
17 Monte's comfortable enjoyment of life or property.

18 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
19 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
20 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
21 unreasonable interference with El Monte and its residents' public rights, including, but not limited
22 to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to be free
23 from disturbance and reasonable apprehension of danger to person or property.

24 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
25 interfered with El Monte and its residents' public rights by, *inter alia*, engaging in a promotion and
26 marketing scheme that pushed the use of opioids for indications not federally approved, and by
27 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
28 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer

1 Defendants failed to comply with federal law.

2 373. Defendants have also unlawfully and intentionally distributed opioids or caused
3 opioids to be distributed within and without El Monte absent effective controls against diversion.
4 Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain
5 effective controls against diversion include Defendants' failure to effectively monitor for
6 suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

7 374. Defendant's unreasonable interference with El Monte residents' public rights
8 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
9 expenditures to combat and address these harms. These damages have been suffered and continue
10 to be suffered directly by El Monte and its residents.

11 375. Defendants' actions have also created a palpable climate of fear, distress,
12 dysfunction and chaos among residents of El Monte where opioid diversion, abuse, and addiction
13 are prevalent and where diverted opioids are used frequently. Specifically, Defendants conduct has
14 caused, among other things, (a) routine separation of children from their parents who have fallen
15 victim to easy access to opioids and/or related crime; (b) children to have easy access and to become
16 addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for
17 loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces
18 and property; (e) property crimes throughout El Monte; (f) employers to lose the value of
19 productive and healthy employees; (g) increased public health and safety costs; (h) a reduction in
20 potential property values within El Monte; and (i) a decrease in tax revenues for El Monte.

21 376. The impact of Defendants' conduct on El Monte is of a continuing nature.
22 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

23 377. Defendants knew or should have known that their actions would lead to the national
24 opioid epidemic and to the resulting injuries to the public rights of El Monte.

25 378. El Monte has sustained a special and peculiar injury because its damages include,
26 *inter alia*, health service expenditures, public safety expenditures, payment of opioid addiction
27 treatment, decreased tax revenues, a reduction in potential property values, and other costs related
28 to opioid addiction treatment and overdose prevention.

1 379. The externalized risks associated with Defendants' nuisance-creating conduct as
2 described herein greatly exceed the internalized benefits.

3 380. Defendants' actions are a direct and proximate contributing cause of the opioid
4 epidemic and the injuries to the public rights of El Monte and its residents.

5 381. Defendants, individually and collectively, are at the very least, a substantial factor
6 in causing the national opioid epidemic and of the injuries to El Monte and its residents.

7 382. The injuries to the public rights of El Monte and its residents are indivisible injuries.

8 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
9 if unabated, will continue to cause an unreasonable interference with public rights of El Monte and
10 its residents.

11 384. Defendants' conduct is ongoing and persistent, and El Monte seeks all damages
12 flowing from Defendants' conduct. El Monte seeks economic losses (direct, incidental, and/or
13 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
14 above. El Monte does not seek damages for the wrongful death, physical personal injury, or
15 emotional distress caused by Defendants' actions.

16 385. Pursuant to Code of Civil Procedure § 731, El Monte requests an order providing
17 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
18 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

19 **SECOND CAUSE OF ACTION**
20 **(Fraud – Against All Defendants)**

21 386. Plaintiff realleges and incorporates herein by reference each and every allegation in
22 paragraphs 1 through 385 above as if set forth fully herein.

23 387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set
24 forth herein

25 388. The Defendants made fraudulent misrepresentations and omissions of material fact.
26 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
27 were intended to induce reliance.

28 389. Those misrepresentations and omissions were known to be untrue by the

1 Defendants, or were recklessly made.

2 390. As alleged herein, the Manufacturer Defendants engaged in false representations
3 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
4 dangers of abuse, and the risks of addiction.

5 391. As alleged herein, Defendants made false statements and/or omissions regarding
6 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
7 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
8 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
9 opioids, within El Monte.

10 392. Defendants made those misrepresentations and omissions in an intentional effort to
11 deceive El Monte and its residents, despite the Defendants' knowledge of the dangers of such use
12 of prescription opioids.

13 393. In addition and independently, Defendants had a duty not to deceive Plaintiff
14 because Defendants had in their possession unique material knowledge that was unknown, and not
15 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

16 394. The Defendants continued making those misrepresentations, and failed to correct
17 those material omissions, despite repeated regulatory settlements and publications demonstrating
18 the false and misleading nature of the Defendants' omissions and/or claims.

19 395. While Defendants had a duty to disclose the above-referenced material facts, they
20 nevertheless concealed them. These false representations and concealed facts were material to the
21 conduct and actions at issue. Defendants made these false representations and concealed facts with
22 knowledge of the falsity of their representations and did so with the intent of misleading El Monte,
23 its residents, the public, and persons on whom these entities relied.

24 396. Defendants intended and had reason to expect under the operative circumstances
25 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
26 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
27 and that these entities would act or fail to act in reasonable reliance thereon.

28 397. El Monte, its residents, and others, did in fact rightfully, reasonably, and justifiably

1 rely on Defendants' representations and/or concealments, both directly and indirectly.

2 398. For instance, doctors, including those serving El Monte and its residents, relied on
3 the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
4 Patients, including residents of El Monte, relied on the Defendants' misrepresentations and
5 omissions in taking prescription opioids for chronic pain relief.

6 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
7 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
8 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
9 effective response to the opioid crisis.

10 400. Defendants' misconduct alleged in this case is ongoing and persistent.

11 401. El Monte has experienced an unprecedented opioid addiction and overdose
12 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
13 services, and lost productivity to El Monte's workforce.

14 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
15 result of Defendants' fraudulent conduct.

16 403. As a direct and foreseeable consequence of Defendants' fraud, El Monte has
17 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
18 opioid addiction treatment and its secondary consequences in excess of those El Monte would have
19 otherwise incurred.

20 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
21 fraudulent, entitling El Monte to punitive damages.

22 **THIRD CAUSE OF ACTION**
23 **(Negligence – Against All Defendants)**

24 405. Plaintiff realleges and incorporates herein by reference each and every allegation in
25 paragraphs 1 through 404 above as if set forth fully herein.

26 406. To establish actionable negligence in California, Plaintiff must show a duty, a breach
27 of that duty, and injury resulting proximately therefrom.

28 407. Defendants have a duty to exercise reasonable care under the circumstances, in light

1 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
2 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
3 and still have, a duty to exercise reasonable care to prevent the threatened harm.

4 408. In addition, Defendants had a duty not to breach the standard of care established
5 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
6 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
7 to abuse, and to develop and maintain systems to detect and report such activity.

8 409. Defendants voluntarily undertook a legal duty to prevent the diversion of
9 prescription opioids by engaging in the distribution of prescription opioids and by making public
10 promises to prevent the diversion of prescription opioids.

11 410. Defendants knew of the serious problem posed by prescription opioid diversion and
12 were under a legal obligation to take reasonable steps to prevent diversion.

13 411. Defendants knew of the highly addictive nature of prescription opioids and of the
14 high likelihood of foreseeable harm to patients and communities, including El Monte, from
15 prescription opioid diversion.

16 412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
17 in accordance with applicable standards of conduct in advertising, marketing, selling, and
18 distributing opioid products in a safe manner to minimize the risk of addiction in patients and
19 resultant harm to those patients, their families and their communities, and to taxpayers and
20 municipal government such as El Monte which must incur enormous expenditures for prevention,
21 treatment, emergency response and law enforcement costs and other foreseeable costs related to the
22 need to address the consequences of a large number of residents that become addicted to opioids as
23 a result of Defendants' conduct.

24 413. As described throughout the Complaint, Defendants breached their duties to
25 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
26 monitor for, failing to report, and filling highly suspicious orders time and again.

27 414. As described throughout the Complaint, in language expressly incorporated herein,
28 Defendants misrepresented their compliance with their duties under the law and concealed their

1 noncompliance and shipments of suspicious orders of opioids to El Monte and destinations from
2 which they knew opioids were likely to be diverted into El Monte, in addition to other
3 misrepresentations alleged and incorporated herein.

4 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
5 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
6 purported benefits of long-term use of opioids for the treatment of chronic pain.

7 416. Manufacturer Defendants knew or should have known, that their affirmative
8 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
9 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
10 representatives, and internal documents, should have put them on notice that such harm was not
11 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
12 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
13 and the public.

14 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
15 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

16 418. Defendants' misconduct alleged in this case is ongoing and persistent.

17 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
18 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
19 great probability of causing substantial harm.

20 420. As is described throughout this Complaint, Defendants acted without even slight
21 diligence or scant care, and with indifference, and were negligent in a very high degree,
22 disregarding the rights and safety of other persons, and said actions have a great probability of
23 causing substantial harm.

24 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
25 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
26 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
27 minimize the risk of addiction in patients and resultant harm to those patients, their families and
28 their communities, and to taxpayers and municipal government such as El Monte, including, but

1 not limited to, the following:

- 2 a. Foreseeability of harm to El Monte: Defendants were aware or reasonably
3 should have been aware of the risk of addiction of a large number of patients in
4 places such as El Monte, and need for their care and treatment and in handling
5 other consequences of their addiction and that such costs would be borne by
6 local governments such as El Monte;
- 7 b. Degree of certainty El Monte suffered harm: El Monte has suffered enormous
8 harm and costs in addressing treatment of addicted patients, including but not
9 limited to expenditures for prevention, treatment, emergency response and law
10 enforcement costs and other foreseeable costs related to the need to address the
11 consequences of a large number of residents that become addicted to opioids as
12 a result of Defendants' conduct;
- 13 c. Closeness of connection between El Monte's harm: The explosion of opioid
14 addiction and the presence of opioid addicted patients in El Monte as a result of
15 Defendants' conduct has resulted in expenditures directly for prevention,
16 treatment, emergency response and law enforcement costs and other foreseeable
17 costs related to the need to address the consequences;
- 18 d. Moral blame attached to Defendants' conduct: Defendants' knew or should have
19 known that their wrongful conduct, actions and omissions would result in an
20 explosion of patients who would become addicted to opioids, and that a vast
21 opioid epidemic would result from the prescription of opioids to tens of millions
22 of patients nationwide, including within El Monte, and that the costs would be
23 borne by the state, county and municipal local governments, while Defendants
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1 profited tens of billions of dollars collectively from the widespread use of
2 prescription opioid products;

3 e. Policy of preventing future harm: As a direct and foreseeable result of
4 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
5 to occur on a vast scale both nationally and locally in places such as El Monte
6 resulting in tremendous harm and cost to the patients, their families and the
7 communities in dealing with this epidemic and crisis, and there is a need to
8 ensure that the costs of such wrongful conduct is borne by Defendants so that
9 parties contemplating such or similar conduct in the future know they will be
10 held responsible for such harm;

11 f. Extent of burden to Defendants: There is no burden to Defendants in that state
12 and other law precludes them from engaging in the conduct alleged herein, and
13 there is no burden from precluding Defendants from profiting from their
14 wrongful conduct and operating within the confines of the law in advertising,
15 marketing, selling and distributing opioid products in a safe manner to minimize
16 the risk of addiction in patients and resultant harm to those patients, their
17 families and their communities, and to taxpayers and municipal government
18 such as Plaintiff El Monte; and

19 g. Consequences to the community of imposing a duty to exercise care with
20 resulting liability for breach: Imposing a duty to not engage in Defendants'
21 wrongful conduct of advertising, marketing, selling and distributing opioid
22 products in an unsafe manner would minimize the risk of addiction in patients,
23 and liability for a breach of this duty would benefit communities such as El
24 Monte;

1 Monte in that they would not have to incur the foreseeable costs of the opioid
2 epidemic gripping the country and the nation.

3
4 422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled
5 substances laws cited above.

6 423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
7 and will continue to suffer economic damages including, but not limited to, significant expenses
8 for security services, emergency, health, prosecution, corrections, and rehabilitation services, as
9 well as the cost of opioid addiction treatment paid by El Monte.

10 424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
11 and will continue to suffer stigma damage, non-physical property damage, and damage to its
12 proprietary interests.

13 425. Defendants' breaches of their duty of care foreseeably and proximately caused
14 damage to El Monte and its residents.

15 426. Manufacturer Defendants are guilty of negligence per se in that the Defendants
16 violated applicable California laws, statutes, and regulations, in the manner in which they
17 advertised, marketed, sold and distributed opioid products.

18 427. Distributor Defendants are guilty of negligence per se in that the Defendants violated
19 California laws, statutes, and regulations designed to protect Plaintiff from the harms it has
20 suffered, including, but not limited to, the following:

- 21 a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug,
22 and Cosmetic Laws, California Health & Safety Code § 110390;
- 23 b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that
24 had been falsely advertised in violation of the Sherman Food, Drug, and
25 Cosmetic Laws, California Health & Safety Code § 110395;
- 26 c. Defendants received in commerce opioids that were falsely advertised or
27 delivered or proffered for delivery opioids that were falsely advertised in
28

violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;

d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;

e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and

f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in El Monte. El Monte, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling El Monte to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

430. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

431. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and

1 purchase of opioids within El Monte, including from opioids foreseeably and deliberately diverted
2 within and into El Monte.

3 432. Plaintiff has expended substantial amounts of money in an effort to remedy or
4 mitigate the societal harms caused by Defendants' conduct.

5 433. These expenditures include, but are not limited to, the provision of emergency
6 medical services and treatment services to people who use opioids.

7 434. These expenditures have helped sustain Defendants' businesses.

8 435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
9 externalities: the cost of the harms caused by Defendants' improper distribution practices.

10 436. Defendants were aware of these obvious benefits, and their retention of the benefit
11 is unjust.

12 437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
13 benefited from those payments because they allowed them to continue providing customers with a
14 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
15 Defendants obtained enrichment they would not otherwise have obtained. Because of their
16 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
17 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
18 lacks a remedy provided by law.

19 438. Defendants' misconduct alleged in this case is ongoing and persistent.

20 439. Defendants have unjustly retained benefits to the detriment of El Monte, and
21 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
22 good conscience.

23 440. El Monte is entitled to restitution and disgorgement from Defendants in an amount
24 to be determined at trial.

25 **FIFTH CAUSE OF ACTION**
26 **(Civil Conspiracy – Against All Defendants)**

27 441. Plaintiff realleges and incorporates herein by reference each and every allegation in
28 paragraphs 1 through 440 above as if set forth fully herein.

1 442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
2 and/or distribution of opioids into California and El Monte.

3 443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
4 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
5 and El Monte.

6 444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
7 report, and prevent suspicious orders of opioids.

8 445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
9 conspiracy by increasing the volume of opioid sales in the United States through creating a market
10 for non-medical use of opioids of epidemic proportions.

11 446. Many of the Manufacturing Defendants are members, participants, and/or sponsors
12 of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized
13 the HDA to give further assistance to the conspiracy.

14 447. The Manufacturing Defendants hid from the general public and suppressed and/or
15 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
16 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead
17 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

18 448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
19 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
20 to commit acts of fraud.

21 449. Indeed, for the Defendants’ fraudulent scheme to work, each of the Defendants had
22 to agree to implement similar tactics.

23 450. By intentionally refusing to report and halt suspicious orders of their prescription
24 opioids, Defendants engaged in a fraudulent scheme.

25 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
26 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
27 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
28 and were actually being diverted into the market of non-medical use.

452. Defendants further unlawfully marketed opioids in California and El Monte in furtherance of that conspiracy to increase profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use through, among other things: (a) the use of “Front Groups” that appeared to be independent of the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c) continuing medical education (“CME”) programs controlled and/or funded by the Defendants; (d) hiring and deploying so-called “key opinion leaders” or “KOLs” who were paid by the Defendants to promote their message; and (e) the “detailing” activities of the Defendants’ sales forces, which directed deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists.

453. Each of the Front Groups helped disguise the role of Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific “literature,” and “treatment guidelines” that promoted the Defendants’ false messages.

454. Each of the KOLs were physicians chosen and paid by each of the Defendants to influence prescribers’ habits by promoting the Defendants’ false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the Defendants’ role in the conspiracy.

455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to and personal relationships with each other through (a) joint participation in lobbying groups, (b) trade industry organizations, (c) contractual relationships, and (d) continuing coordination of activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work together with the Defendants to advance the conspiracy.

456. Defendants’ conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in Plaintiff’s Counts for violations California Statutes. Such allegations are specifically incorporated herein.

1 457. Defendants acted with a common understanding or design to commit unlawful acts,
2 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
3 proximately caused the injuries alleged herein.

4 458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
5 reasonable or lawful excuse.

6 459. Defendants conduct in furtherance of the conspiracy described herein was not mere
7 parallel conduct because each Defendant acted directly against their commercial interests in not
8 reporting the unlawful distribution practices of their competitors to the authorities, which they had
9 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
10 actual or tacit agreement between the Defendants that they would not report each other to the
11 authorities so they could all continue engaging in their unlawful conduct.

12 460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
13 thereof, caused the direct and foreseeable losses alleged herein.

14 461. Defendants' misconduct alleged in this case is ongoing and persistent.

15 462. As a result of Defendants' conspiracy, El Monte is entitled to compensatory
16 damages in an amount to be proved at trial.

17 463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
18 fraudulent, entitling El Monte to punitive damages.

19
20
21 **SIXTH CAUSE OF ACTION**
22 **(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

23 464. Plaintiff realleges and incorporates herein by reference each and every allegation in
24 paragraphs 1 through 463 above as if set forth fully herein.

25 465. California Business & Professions Code § 17500 makes it unlawful for a business
26 to make, disseminate, or cause to be made or disseminated to the public "any statement, concerning
27 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
28 exercise of reasonable care should be known, to be untrue or misleading."

1 466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
2 designed to disseminate false or misleading statements designed to promote the belief that opioid
3 drugs could safely be used in a non-addictive manner.

4 467. By way of example, Actavis's predecessor created a patient brochure for Kadian in
5 2007 that deceptively stated that needing to up one's dose to achieve the same treatment outcome
6 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

7 468. Actavis's predecessor caused a patient education brochure, Managing Chronic Back
8 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
9 claimed that it is "less likely if you have never had an addiction problem."

10 469. Cephalon and Purdue sponsored research and publications that falsely and
11 deceptively stated opioids did not have "ceiling dose."

12 470. Purdue created websites, available to the public that instructed patients to seek new
13 medical providers out if their current provider would not increase their dose.

14 471. Defendants' false and deceptive advertising practices resulted in increased opioid
15 dosages being prescribed to El Monte's residents, increasing the incidence of opioid addiction and
16 overdose in El Monte.

17 472. Distributor Defendants also repeatedly omitted material information and/or falsely
18 represented that they were effectively preventing diversion and were monitoring, reporting, and
19 preventing suspicious orders.

20 473. As alleged above, Defendants' statements about the risks associated with opioid use
21 were not supported by or were contrary to the scientific evidence.

22 474. As alleged above, each Defendant's conduct, separately and collectively, was likely
23 to deceive California payors who purchased or covered the purchase of opioids.

24 475. El Monte seeks restitution and injunctive relief under California Business &
25 Professions Code § 17535.

26 476. El Monte also seeks an order assessing a civil penalty of two thousand five hundred
27 dollars (\$2,500) against Defendants for each violation of California's False Advertising Law
28 pursuant to California Business & Professions Code § 17536.

SEVENTH CAUSE OF ACTION**(Negligent Failure to Warn— Against Manufacturer Defendants)**

477. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 476 above as if set forth fully herein.

478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable and ordinary care and skill, as well as in accordance with applicable standards of conduct in adequately warning the medical profession about the risk of addiction from the use of opioid products, and not to overpromote and over-market opioid products in a manner so as to nullify, cancel out, and render meaningless any written warnings given about the risk of addiction from the use of opioid products.

479. Defendants breached their duty to exercise reasonable and ordinary care by failing to adequately warn the medical profession about the risk of addiction from the use of opioid products, including by overpromoting and over-marketing opioid products in a manner so as to nullify, cancel out and render meaningless any warnings in the labels about any addiction risk. Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid products in situations and for patients who should not have been using those drugs or should have used them only as a last resort before other means were used or other less addictive and dangerous drugs were prescribed.

480. As a direct and proximate consequence of Defendants' negligent failure to warn, and overpromoting and over-marketing the use of prescription opioid products, there is now a national opioid addiction epidemic, including in El Monte. The People, as a further direct and proximate consequence and result thereof, sustained injuries and damages including but not limited to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, opioid disposal programs, and measures for prevention of further opioid abuse and addiction.

481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling El Monte to punitive damages.

EIGHTH CAUSE OF ACTION
(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler Defendants)

482. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 481 above as if set forth fully herein.

483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will possess a right to payment from Purdue.

484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors, including Plaintiff.

486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void them pursuant to California Civil Code § 3439.04(a)(1).

NINTH CAUSE OF ACTION
(Civil Conspiracy – Against Purdue and Sackler Defendants)

487. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 486 above as if set forth fully herein.

488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection of its judgment against Purdue entered in this action.

489. After the Sackler Defendants became aware in or about 1999 that Purdue faced potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other

1 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
2 Defendants and their extended family.

3 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
4 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
5 to commit acts of fraud.

6 491. Purdue and the Sackler Defendants acted with a common understanding or design
7 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
8 excuse, which directly and proximately caused the injuries alleged herein.

9 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
10 unlawfully, and without a reasonable or lawful excuse.

11 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
12 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
13 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
14 judgment entered in this action.

15 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
16 compensatory damages in an amount to be proved at trial.

17 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
18 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

19
20 **PRAYER FOR RELIEF**

21 WHEREFORE, El Monte and the People respectfully request judgment in their favor
22 granting the following relief:

- 23 a) Entering Judgment in favor of El Monte and the People in a final order against
24 each of the Defendants;
- 25 b) An award of actual and consequential damages in an amount to be determined at
26 trial;
- 27 c) An order obligating Defendants to disgorge all revenues and profits derived from
28 their scheme;

- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff’s judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;
- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;

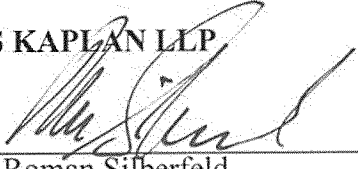
- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and
- v) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Dated: March 27, 2019

ROBINS KAPLAN LLP

By: _____


Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT I

SUMMONS (CITACION JUDICIAL)

SUM-100

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment
form is attached)

YOU ARE BEING SUED BY PLAINTIFF: CITY OF COSTA MESA; and
(LO ESTÁ DEMANDANDO EL DEMANDANTE): THE PEOPLE OF THE
STATE OF CALIFORNIA, by and through Costa Mesa City
Attorney Kimberly Hall Barlow

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. ¡AVISO! Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es):

San Francisco County Superior Court
Civic Center Courthouse
400 McAllister Street
San Francisco, CA 94102-4515

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800
Lucas A. Messenger, Bar No. 217645
ROBINS KAPLAN LLP
Los Angeles, CA 90067

DATE:

(Fecha) MAR 28 2019

CLERK OF THE COURT

Clerk, by
(Secretario)

DE LA VEGA-NAVARRO, Rossal Deputy
(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):
3. ☐ on behalf of (specify):
under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other (specify):
4. ☐ by personal delivery on (date):

[SEAL]

SUM-200(A)

SHORT TITLE: City of Costa Mesa, et al. v. Purdue
Pharma L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
THE PURDUE FREDERICK COMPANY;
RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER FAMILY;
JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER FAMILY;
MORTIMER D.A. SACKLER, an individual;
KATHE A. SACKLER, an individual;
IRENE SACKLER LEFCOURT, an individual;
BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
DAVID A. SACKLER, an individual;
CEPHALON, INC.;
TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
JANSSEN PHARMACEUTICALS, INC.;
JOHNSON & JOHNSON;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS INC.;
ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS PHARMA, INC.;
ACTAVIS LLC;
ALLERGAN PLC;
ALLERGAN, INC.;
ALLERGAN USA, INC.;
INSYS THERAPEUTICS, INC.;
MALLINCKRODT, PLC;
MALLINCKRODT, LLC;
CARDINAL HEALTH, INC.;
AMERISOURCEBERGEN CORPORATION;
MCKESSON CORPORATION; and
DOES 1-100, inclusive,

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

ENDORSED
FILED
Superior Court of California
County of San Francisco
MAR 28 2019
CLERK OF THE COURT
BY: ROSSALY DE LA VEGA
Deputy Clerk

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Attorneys for Plaintiffs City of Costa Mesa and The
People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN FRANCISCO

CITY OF COSTA MESA; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Costa
Mesa City Attorney Kimberly Hall Barlow,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

Case No. **CGC-19-574865**

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;
8. FRAUDULENT TRANSFER; and

1 SACKLER, an individual; IRENE
 2 SACKLER LEFCOURT, an individual;
 3 BEVERLY SACKLER, an individual and
 4 as trustee for TRUST FOR THE BENEFIT
 5 OF MEMBERS OF THE RAYMOND
 6 SACKLER FAMILY; THERESA
 7 SACKLER, an individual; DAVID A.
 8 SACKLER, an individual; CEPHALON,
 9 INC.; TEVA PHARMACEUTICAL
 10 INDUSTRIES, LTD.; TEVA
 11 PHARMACEUTICALS USA, INC.;
 12 JANSSEN PHARMACEUTICALS, INC.;
 13 JOHNSON & JOHNSON; ORTHO-
 14 MCNEIL-JANSSEN
 15 PHARMACEUTICALS, INC.; JANSSEN
 16 PHARMACEUTICA, INC.; ENDO
 17 HEALTH SOLUTIONS INC.; ENDO
 18 PHARMACEUTICALS INC.; ACTAVIS
 19 PLC; WATSON PHARMACEUTICALS,
 20 INC.; WATSON LABORATORIES, INC.;
 21 ACTAVIS PHARMA, INC.; ACTAVIS
 22 LLC; ALLERGAN PLC; ALLERGAN,
 23 INC.; ALLERGAN USA, INC.; INSYS
 24 THERAPEUTICS, INC.;
 25 MALLINCKRODT, PLC;
 26 MALLINCKRODT, LLC; CARDINAL
 27 HEALTH, INC.;
 28 AMERISOURCEBERGEN
 CORPORATION; MCKESSON
 CORPORATION; and
 DOES 1-100, inclusive,

Defendants.

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	12
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Costa Mesa Through Illicit Channels.....	58
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Costa Mesa Through Illicit Channels	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Costa Mesa	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	81
A.	The Marketing Scheme	81
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

1 services, and detention centers; (d) increased burden on Costa Mesa's code enforcement programs;
2 (e) an influx of so-called sober living homes whose operators take advantage of addicts both local
3 and out-of-state, causing negative impacts to neighborhoods, harm to residents of the sober living
4 homes and an increase in homelessness, all leading to substantial costs to Costa Mesa and the
5 People for provision of shelter, low income housing and related social services; and (f) extensive
6 clean-up of public parks, spaces, and facilities. At the same time, Costa Mesa has seen a reduction
7 to tax revenues caused by the epidemic created by the Defendants. Almost every citizen of Costa
8 Mesa has been affected. The resulting damage to Costa Mesa was directly and foreseeably caused
9 by Defendants' actions.

10 7. Costa Mesa brings this action in part to address a terrible tragedy the City has
11 endured. On November 5, 2018, Costa Mesa lost an honored son and public servant, Costa Mesa
12 Fire Captain Mike Kreza. Captain Kreza, survived by his wife and three young daughters, died two
13 days after being struck by a driver under the influence of prescription opioids. The driver had
14 received the opioids from a physician under federal indictment for supplying prescription opioids
15 to patients without medical examination. The physician is facing charges for drug trafficking and
16 illegal distribution of controlled substances. Costa Mesa has been directly injured by the loss of
17 Captain Kreza, including costs for training and hiring a replacement, as well as pension and death
18 benefits.

19 8. These increased costs could have been—and should have been—prevented by the
20 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
21 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
22 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
23 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
24 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
25 protecting opioids from theft, misuse, and diversion.

26 9. Instead of acting with reasonable care and in compliance with their legal duties,
27 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
28 process.

10. At the same time, Defendants flooded the market with false statements designed to persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those claims were false.³

11. Defendants' actions have not only caused significant costs, but have also created a palpable climate of fear, distress, dysfunction and chaos among Costa Mesa residents where opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used frequently.

12. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

II. THE PARTIES

A. The Plaintiffs

13. Costa Mesa, California, by and through its attorneys hereto and its City Attorney, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

14. Costa Mesa has standing to recover damage incurred because of Defendants' actions and omissions. Costa Mesa has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

15. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

16. PURDUE PHARMA L.P. is a limited partnership organized under the laws of

³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at <http://turnthetidex.org/> (last accessed December 18, 2017).

1 Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business
2 in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation
3 with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma
4 Inc., and The Purdue Frederick Company are referred to collectively as “Purdue”).

5 17. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin,
6 MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States,
7 including California. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s annual sales
8 of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006
9 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
10 (painkillers).

11 18. In May 2007, Purdue entered into a stipulated final judgment with the State of
12 California, acting by and through the California Attorney General, based principally on Purdue’s
13 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
14 final judgment (the “Purdue Final Judgment”). Through this Complaint, the People do not seek to
15 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
16 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
17 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
18 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
19 2007. The People, however, do assert claims arising under California law independent of the Purdue
20 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

21 19. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
22 son of Purdue founder Raymond Sackler, and beginning in the 1990’s, served as a member of the
23 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
24 Trust for the Benefit of Members of the Raymond Sackler Family (the “Raymond Sackler Trust”),
25 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
26 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

27 _____
28 ⁴ Long-acting or extended release (“ER” or “ER/LA”) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (“IR”) opioids, last for approximately 4-6 hours.

20. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the Raymond Sackler Trust.

21. Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

22. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

24. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

25. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

26. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a

1 Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

2 27. CEPHALON, INC. is a Delaware corporation with its principal place of business in
3 Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (“Teva Ltd.”) is an
4 Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva
5 Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (“Teva USA”) is a wholly
6 owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in
7 Pennsylvania.

8 28. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq
9 and Fentora in the United States, including California. Significantly, the FDA only approved Actiq
10 and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-
11 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
12 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
13 promotion of Actiq and two other drugs and agreed to pay \$425 million.

14 29. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
15 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
16 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
17 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
18 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
19 medicines” division. The FDA approved prescribing information and medication guide, which is
20 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
21 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
22 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
23 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
24 covering certain co-pay costs.

25 30. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
26 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
27 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
28 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion

1 of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd.
 2 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
 3 Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its
 4 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
 5 Ltd. would conduct those companies' business in the United States itself. Upon information and
 6 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
 7 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
 8 Cephalon, Inc. are referred to as "Cephalon"). Teva Branded Pharmaceutical Products R&D, Teva
 9 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
 10 Marketing are registered to do business in California with the California Secretary of State.

11 31. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its
 12 principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of
 13 JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in
 14 New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now
 15 known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of
 16 business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen
 17 Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in
 18 Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than
 19 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's
 20 products. Upon information and belief, J&J controls the sale and development of Janssen
 21 Pharmaceutical's products and Janssen's profits inure to J&J's benefit. (together, Janssen
 22 Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc.,
 23 and J&J are referred to as "Janssen").

24 32. Janssen manufactures, promotes, sells, and distributes drugs in the United States,
 25 including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted
 26 for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold
 27 the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172
 28 million in sales in 2014.

33. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

34. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, including California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA) International Trade Co., is registered to do business in California with the California Secretary of State.

35. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013, and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA, INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as “Actavis”).

36. Actavis manufactures, promotes, sells, and distributes opioids, including the

1 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
2 in the United States, including California. Actavis acquired the rights to Kadian from King
3 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
4 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
5 California Secretary of State.

6 37. ALLERGAN PLC is a public limited company incorporated in Ireland with its
7 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
8 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
9 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
10 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,
11 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
12 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
13 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
14 California with the California Secretary of State.

15 38. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
16 principal place of business located in Chandler, Arizona.

17 39. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source
18 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
19 United States, including California. Subsys was indicated by the FDA for the treatment of
20 breakthrough cancer pain that other opioids could not eliminate.

21 40. In May 2018, an Insys sales representative admitted to taking part in a scheme to
22 bribe physicians with purported speaking fees for marketing and education events in exchange for
23 them prescribing Subsys for off-label uses. Insys’ founder and several other former Insys executives
24 were recently indicted by federal prosecutors on racketeering charges, alleging that these
25 individuals approved and fostered fraudulent behavior against insurance companies and also
26 conspired to bribe practitioners in various states. Insys Group is registered to do business in
27 California with the California Secretary of State.

28 41. MALLINCKRODT, PLC is an Irish public limited company headquartered in

1 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
2 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
3 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
4 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

5 42. Mallinckrodt manufactures, markets, and sells drugs in the United States including
6 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
7 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
8 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
9 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
10 Products are registered to do business in California with the California Secretary of State.

11 43. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and
12 Mallinckrodt are the “Manufacturer Defendants.”

13 **C. The Distributor Defendants**

14 44. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company
15 incorporated under the laws of Ohio and with a principal place of business in Ohio.

16 45. Cardinal distributes prescription opioids to providers and retailers, including in
17 California. Cardinal has engaged in consensual commercial dealings with Costa Mesa and its
18 residents, and has purposefully availed itself of the advantages of conducting business with and
19 within Costa Mesa. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health
20 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with
21 the California Secretary of State.

22 46. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly
23 traded company incorporated under the laws of Delaware and with a principal place of business in
24 Pennsylvania.

25 47. AmerisourceBergen distributes prescription opioids to providers and retailers,
26 including in California. AmerisourceBergen has engaged in consensual commercial dealings with
27 Costa Mesa and its residents, and has purposefully availed itself of the advantages of conducting
28 business with and within Costa Mesa. AmerisourceBergen is in the chain of distribution of

1 prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen
2 Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services
3 Corporation are registered to do business in California with the California Secretary of State.

4 48. MCKESSON CORPORATION (“McKesson”) is a publicly traded company
5 incorporated under the laws of Delaware and with a principal place of business in San Francisco,
6 California.

7 49. McKesson distributes prescription opioids to providers and retailers, including in
8 California. McKesson has engaged in consensual commercial dealings with Costa Mesa and its
9 residents, and has purposefully availed itself of the advantages of conducting business with and
10 within Costa Mesa. McKesson is in the chain of distribution of prescription opioids. McKesson
11 Corporation is registered to do business in California with the California Secretary of State.

12 50. The data which reveals and/or confirms the identity of the other wrongful opioid
13 distributor is hidden from public view in the DEA’s confidential ARCOS database. *See Madel v.*
14 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
15 voluntarily disclose the data necessary to identify with specificity the transactions which will form
16 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

17 51. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
18 market share for the distribution of prescription opioids. The “Big 3” are Fortune 500 corporations
19 listed on the New York Stock Exchange and their principal business consists of the nationwide
20 wholesale distribution of prescription drugs. *See Fed. Trade Comm’n v. Cardinal Health, Inc.*, 12
21 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
22 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
23 suspicious orders. Costa Mesa has reason to believe each has engaged in unlawful conduct which
24 resulted in the distribution, dispensing, and diversion of prescription opioids into Costa Mesa. Costa
25 Mesa names each of the “Big 3” herein as defendants and places the industry on notice that Costa
26 Mesa is acting to abate the public nuisance plaguing its community. Distributor Defendants have
27 had substantial contacts and business relationships with the People. Distributor Defendants have
28 purposefully availed themselves of business opportunities within Costa Mesa.

52. Collectively, AmerisourceBergen, Cardinal, and McKesson are the “Distributor Defendants.”

D. The Doe Defendants

53. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive, and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein.

III. JURISDICTION AND VENUE

54. This Court has jurisdiction over this action. Defendants are engaging in false and misleading advertising, negligent acts, and creating or assisting in the creation of a public nuisance in Costa Mesa, and the People through their attorneys have the right and authority to prosecute this case on behalf of the People.

55. Venue is proper in this Court because Defendants transact business in California and Costa Mesa, and some of the acts complained of occurred in this venue. Furthermore, Defendant Distributor McKesson’s principal place of business is in California, and McKesson conducted business and continues to do business throughout the United States and in the State of California by regularly and continuously distributing prescription opioids throughout the State of California, including in Costa Mesa.

IV. GENERAL FACTUAL ALLEGATIONS

A. An Overview of the Opioid Epidemic

56. The term “opioid” includes all drugs derived from the opium poppy. The United States Food and Drug Administration describes opioids as follows: “Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right condition and when used properly.

1 But when misused or abused, opioids can cause serious harm, including addiction, overdose, and
2 death.”⁵

3 57. Prescription opioids with the highest potential for addiction are listed under
4 Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such
5 as codeine and morphine, also known generally as “opiates”), partially synthetic derivatives (such
6 as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

7 58. Historically, opioids were considered too addictive and debilitating for the treatment
8 of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,
9 director of Johns Hopkins University’s Center for Drug Safety and Effectiveness, “[opioids] have
10 very, very high inherent risks . . . and there’s no such thing as a fully safe opioid.”⁶

11 59. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
12 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
13 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

14 60. Before the 1990s, generally accepted standards of medical practice dictated that
15 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
16 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
17 patients’ ability to overcome pain and function, as well as evidence of *greater* pain complaints as
18 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
19 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
20 generally did not prescribe opioids for chronic pain.

21 61. The market for chronic pain patients, however, was much larger, and to take
22 advantage of it, the Defendants had to change doctors’ general reluctance to prescribe opioids for
23 chronic pain.⁷

24 _____
25 ⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

26 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

27 ⁷ See Harriet Ryan et al., ‘*You want a description of hell?*’ *OxyContin’s 12-hour problem*, L.A. Times
28 (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

62. As described herein, Defendants engaged in conduct that directly caused doctors to prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their obligations to prevent diversion of the highly addictive substance.

63. As a result of Defendants' wrongful conduct, the number of opioid prescriptions increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough for every person in the United States to have a bottle of pills. This represents an increase of 300% since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions were dispensed per 100 persons.

64. Many Americans, including Californians and residents of Costa Mesa, are now addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United States, an increase of more than 22 percent over the previous year. The New York Times reported in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly opioids are "everywhere" and are easily mistaken as candy.⁸ The opioid epidemic has been declared a public health emergency by the President of the United States. The wave of opioid addiction was created by the increase in prescriptions.

65. One in 4 Americans receiving long-term opioid therapy struggles with opioid addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the NIH's National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder. Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about 80 percent of people who use heroin first misused prescription opioids.

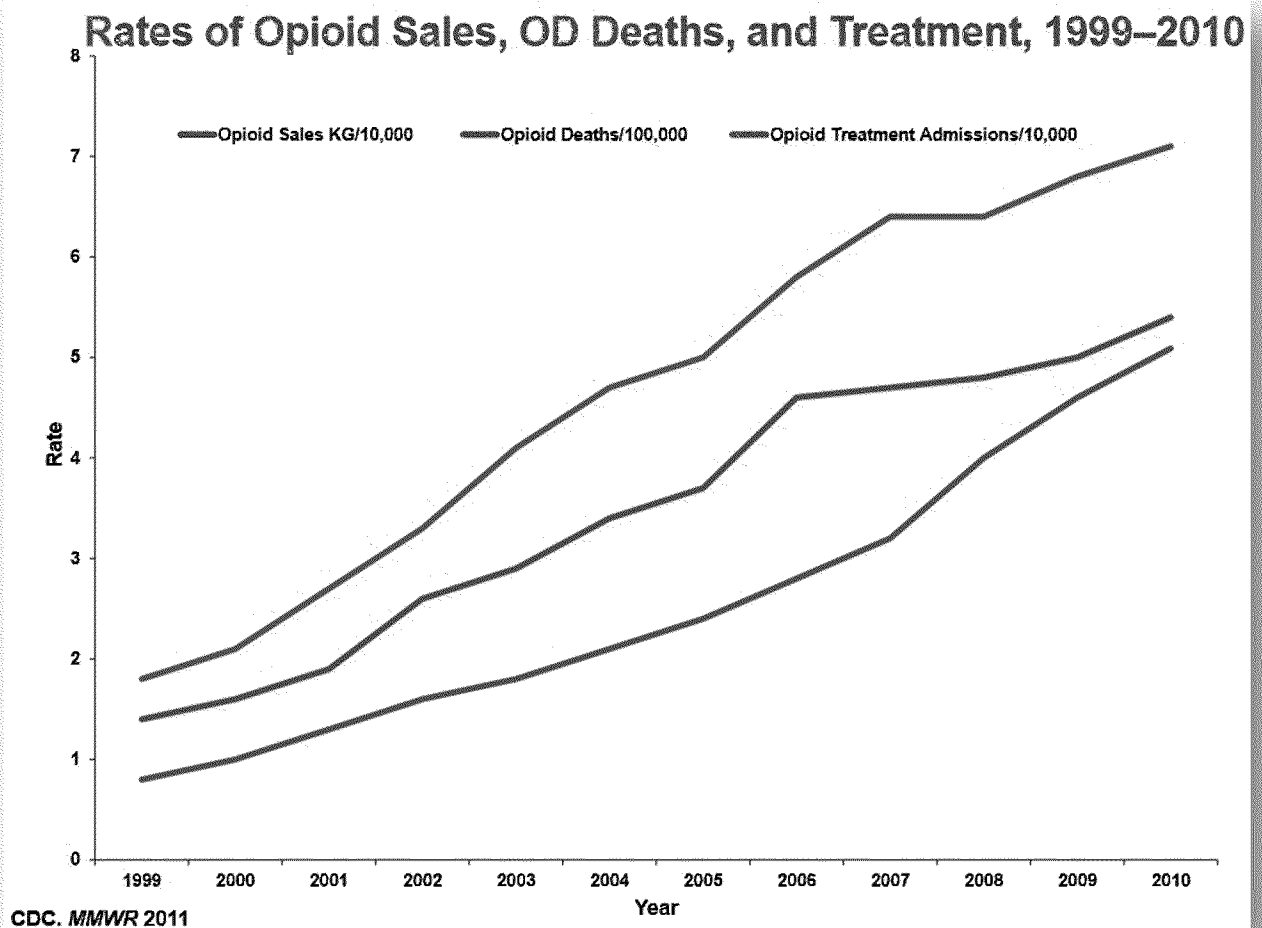
66. Drug overdose deaths among all Americans increased more than 200 percent between 1999 and 2015.

67. Deaths from prescription opioids have quadrupled in the past 20 years. In California, there were 4,654 total opioid overdose deaths in 2016.⁹

⁸ Julie Turkewitz, "The Pills are Everywhere:" *How the Opioid Crisis Claims Its Youngest Victims*, N.Y. Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html> (last accessed January 4, 2018).

⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at

68. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



69. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years.

¹⁰ <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

1 In California, 355 overdose deaths in 2016 involved heroin.¹¹

2 70. Prescription opioid abuse “is a serious national crisis that affects public health as
3 well as social and economic welfare.” The economic burden of prescription opioid misuse alone on
4 the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction
5 treatment, and criminal justice expenditures.¹²

6 **B. The Manufacturer Defendants Spread False or Misleading Information About**
7 **the Safety of Opioids**

8 71. Each Manufacturer Defendant developed a well-funded marketing scheme based on
9 deception to persuade doctors and patients that opioids can and should be used to treat chronic pain
10 without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients
11 who are much more likely to become addicted. In connection with this scheme, each Manufacturer
12 Defendant spent, and continues to spend, millions of dollars on promotional activities and materials
13 that falsely deny or minimize the risks of opioids.

14 72. The Manufacturer Defendants employed the same marketing plans and strategies,
15 and deployed the same messages in and around California, including in Costa Mesa, as they did
16 nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding
17 and overseeing “core message” development on a national basis. This comprehensive approach
18 ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered
19 across marketing channels—including detailing visits, speaker events, and advertising—and in
20 each sales territory. The Manufacturer Defendants consider this high level of coordination and
21 uniformity crucial to successfully marketing their prescription drugs.

22 73. To increase the impact of their deceptive marketing schemes, on information and
23 belief the Manufacturer Defendants coordinated and created unified marketing plans to ensure that
24 the Manufacturer Defendants’ messages were consistent with one another and effective across all
25

26 ¹¹ See National Institute of Drug Abuse, California Opioid Summary, available at
27 <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>,
(last accessed August 13, 2018).

28 ¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 their marketing efforts.

2 74. The deceptive marketing schemes included, among others: (a) false or misleading
3 direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known
4 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
5 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
6 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
7 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
8 carried a low, or no, risk of addiction.

9 75. Contrary to the language on their drugs’ labels regarding the serious risks associated
10 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
11 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
12 of actual addiction began appearing, and advocated that the signs of addiction should be treated
13 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
14 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
15 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
16 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
17 opioid use, including the supposed ability of opioids to improve function and quality of life, even
18 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
19 claims.

20 76. These statements were not only unsupported by or contrary to the scientific
21 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
22 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
23 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

24 77. The Manufacturer Defendants began their marketing schemes decades ago and
25 continue them today.

26 78. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
27 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
28 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue

1 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon
 2 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
 3 . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
 4 for legitimate pain.”¹⁴

5 79. On information and belief, as a part of their deceptive marketing schemes, the
 6 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
 7 populations in the United States, including California.

8 80. For example, on information and belief, the Manufacturer Defendants focused their
 9 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
 10 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
 11 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
 12 the Manufacturer Defendants’ misrepresentations.

13 81. On information and belief, the Manufacturer Defendants also targeted vulnerable
 14 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

15 82. The Manufacturer Defendants targeted these vulnerable patients even though the
 16 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
 17 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
 18 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
 19 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
 20 term opioid use for elderly patients and recommended that doctors use “additional caution and
 21 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
 22 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
 23 disorder, which interact dangerously with opioids.

24 83. The Manufacturer Defendants intentionally continued their conduct, as alleged
 25 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
 26

27 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David
 28 Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

¹⁴ Murthy, *supra* note 3.

1 and damages alleged herein.

2 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
3 **Marketing of Opioids**

4 84. Each Manufacturer Defendant conducted, and continues to conduct, direct
5 marketing consisting of advertising campaigns touting the purported benefits of their branded
6 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
7 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

8 85. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
9 benefits of opioids for chronic pain. For example:

- 10 a. Endo, on information and belief, has distributed and made available on its website
11 opana.com a pamphlet promoting Opana ER with photographs depicting patients
12 with physically demanding jobs like construction worker and chef, misleadingly
13 implying that the drug would provide long-term pain-relief and functional
14 improvement.
- 15 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
16 for OxyContin in 2012 in medical journals. These ads featured chronic pain
17 patients and recommended OxyContin for each. One ad described a "54-year-old
18 writer with osteoarthritis of the hands" and implied that OxyContin would help the
19 writer work more effectively.

20 86. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
21 misleading representations in New York, they continued to disseminate them elsewhere throughout
22 the United States, including California.

23 87. The direct advertising disseminated by the Manufacturer Defendants failed to
24 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
25 support many of their claims.

26 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
27 **to Spread False and Misleading Information About Opioids**

28 88. Each Manufacturer promoted the use of opioids for chronic pain through
"detailers"—sophisticated and specially trained sales representatives who visited individual doctors
and medical staff in their offices—and small group speaker programs.

89. The Manufacturer Defendants invested heavily in promoting the use of opioids for

1 chronic pain through detailers and small group speaker programs.

2 90. The Manufacturer Defendants devoted massive resources to direct sales contacts
3 with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in
4 excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what
5 they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed
6 at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible
7 for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

8 91. On information and belief, these detailers have spread and continue to spread
9 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
10 including thousands of doctors in California, in the following manner:

- 11 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 12 b. Describe their opioid products as “steady state” – falsely implying that these
13 products are less likely to produce the high and lows that fuel addiction – or as
14 less likely to be abused or result in addiction;
- 15 c. Tout the effectiveness of screening or monitoring patients as a strategy for
16 managing opioid abuse and addiction;
- 17 d. State that there is no maximum dose and that doctors can safely increase doses
18 without disclosing the significant risks to patients at higher doses;
- 19 e. Discuss “pseudoaddiction;”
- 20 f. State that patients would not experience withdrawal if they stopped using their
21 opioid products; and
- 22 g. State that abuse-deterrent formulations are tamper- or crush-resistant and
23 harder to abuse or misuse.

24 92. Because these detailers must adhere to scripts and talking points drafted by the
25 Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer
26 Defendants’ detailers made and continue to make these misrepresentations to the thousands of
27 California doctors they have visited and continue to visit. The Manufacturer Defendants have not
28 corrected this misinformation.

93. The Manufacturer Defendants’ detailing to doctors was highly effective in
generating the national proliferation of prescription opioids. On information and belief, the

1 Manufacturer Defendants used sophisticated data mining and intelligence to track and understand
2 the rates of initial prescribing and renewal by individual doctors, allowing specific and individual
3 targeting, customizing, and monitoring of their marketing efforts.

4 94. The Manufacturer Defendants also identified doctors to serve on their speakers'
5 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
6 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
7 they were providing unbiased and medically accurate presentations when they were in fact
8 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
9 presentations conveyed misleading information, omitted material information, and failed to correct
10 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
11 including addiction risks.

12 95. Each Manufacturer Defendant devoted and continues to devote massive resources
13 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
14 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
15 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
16 and \$2 million by Actavis.

17 96. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
18 influence. On information and belief, more frequent prescribers are generally more likely to have
19 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
20 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
21 Defendant's opioid products.

22 97. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
23 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
24 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
25 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
26 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
27 The FDA also found that "[t]hese violations are a concern from a public health perspective because
28

1 they suggest that the product is safer and more effective than has been demonstrated.”¹⁵

2 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 3 **Seemingly Independent Third Parties that Disseminated Unbranded**
 4 **Advertising Created by the Manufacturer Defendants**

5 98. The Manufacturer Defendants also deceptively marketed opioids in California
 6 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 7 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 8 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 9 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 10 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 11 promote opioids for the treatment of chronic pain as non-addictive.

12 99. The extent of the financial ties between the opioid industry and third-party advocacy
 13 groups is stunning. A recent report released by the United State Senate Homeland Security and
 14 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 15 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 16 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 17 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 18 messaging.” The report concluded that “many of the groups described in this report may have
 19 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

20 100. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 21 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 22 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 23 advertising to give the false appearance that the deceptive messages came from an independent and
 24

25 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug
 26 Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 29, 2017).

27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
2 used third parties that they funded, directed, and controlled to carry out and conceal their scheme
3 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

4 101. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
5 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
6 unbranded advertising stated that “People who take opioids as prescribed usually do not become
7 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
8 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
9 medical use.”

10 102. In addition to using third parties to disguise the source of their misinformation
11 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
12 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
13 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
14 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
15 Defendants because their public positions supported the use of opioids to treat chronic pain.

16 103. Manufacturer Defendants paid these KOLs to serve as consultants or on their
17 advisory boards and to give talks or present continuing medical education programs (CMEs), and
18 their support helped these KOLs become respected industry experts. As they rose to prominence,
19 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
20 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
21 became dependent on continuing to promote a pro-opioid message.

22 104. Pro-opioid doctors like the KOLs are one of the most important avenues that the
23 Manufacturer Defendants use to spread their false and misleading statements about the risks and
24 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
25 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
26 and reliable support for treatment of chronic pain through chronic opioid therapy without
27 significant risk of addiction.

28 105. For example, the New York Attorney General (“NY AG”) found in its settlement

1 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
2 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
3 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
4 objectivity of the testimonials.

5 106. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
6 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
7 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
8 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
9 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
10 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
11 opioid therapy that acknowledged risks of addiction.

12 107. The Manufacturer Defendants' KOLs also served on committees that developed
13 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
14 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
15 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
16 were created, and they are not supported by the scientific evidence today. Defendants were able to
17 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
18 Guideline recognizes that treatment guidelines can "change prescribing practices."

19 108. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
20 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
21 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
22 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
23 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
24 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 “destigmatize” opioid. Dr. Portenoy conceded that “[d]ata about the effectiveness of opioids does
2 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
3 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
4 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

5 109. Dr. Portenoy also made frequent media appearances promoting opioids and
6 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
7 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
8 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
9 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
10 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
11 personal history, of substance abuse, and does not have a history in the family of substance abuse,
12 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
13 person is not going to become addicted.”¹⁹

14 110. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
15 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
16 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
17 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
18 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
19 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
20 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
21 including nearly \$2 million from Cephalon.

22 111. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
23 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
24 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
25 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
2 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
3 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
4 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
5 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
6 their influence and control.

7 112. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
8 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
9 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
10 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
11 doctors in Costa Mesa and doctors treating residents of Costa Mesa.²⁰

12 113. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
13 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
14 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
15 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
16 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
17 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
18 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
19 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
20 to give patients more medication."²²

21 114. On information and belief, the Manufacturer Defendants also entered into
22 arrangements with seemingly unbiased and independent patient and professional organizations to
23 promote opioids for the treatment of chronic pain. Under the direction and control of the
24 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
25

26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

28 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

1 American Pain Foundation (“APF”)²³ and the American Academy of Pain Medicine—generated
2 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
3 evidence did not support these guidelines, materials, and programs at the time they were created,
4 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
5 the 2016 CDC Guideline.

6 115. The Manufacturer Defendants worked together through Front Groups to spread their
7 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
8 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
9 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
10 on behalf of both the opioid industry and the Front Groups.

11 116. On information and belief, these Front Groups also assisted the Manufacturer
12 Defendants by responding to negative articles, advocating against regulatory or legislative changes
13 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
14 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

15 117. These Front Groups depended on the Manufacturer Defendants for funding and, in
16 some cases, for their very survival. On information and belief, the Manufacturer Defendants
17 exercised control over programs and materials created by these groups by collaborating on, editing,
18 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
19 Defendants made sure that the Front Groups would only generate messages the Manufacturer
20 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
21 experts serving the needs of their members, whether patients suffering from pain or doctors treating
22 those patients.

23 118. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
24 including many of the same ones. Several of the most prominent Front Groups are described in
25 greater detail below, but there are many others, including the American Pain Society, American
26 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,

27 _____
28 ²³ Dr. Portenoy was a member of the board of the APF.

²⁴ See Neuman & Kodjack, *supra* note 16.

1 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

2 119. Organizations, including the U.S. Senate Finance Committee, began to investigate
3 the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise,
4 between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent
5 of its funding from the drug and medical-device industry, and “its guides for patients, journalists
6 and policymakers had played down the risks associated with opioid painkillers while exaggerating
7 the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic
8 circumstances.”

9 120. Another one of the Front Groups for the Manufacturer Defendants was the American
10 Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding
11 of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored
12 and hosted medical education programs essential to the Manufacturer Defendants’ deceptive
13 marketing of chronic opioid therapy.

14 121. AAPM received substantial funding from opioid manufacturers. For example,
15 AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of
16 other funding) to participate. The benefits included allowing members to present educational
17 programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual
18 meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual
19 event as an “exclusive venue” for offering education programs to doctors. Membership in the
20 corporate relations council also allows drug company executives and marketing staff to meet with
21 AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon
22 were members of the council and presented deceptive programs to doctors who attended these
23 annual events.

24 122. On information and belief, AAPM is viewed internally by Endo as “industry

25 _____
26 ²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E.
Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

27 ²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*,
28 Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last
accessed December 19, 2017).

1 friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM
2 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
3 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
4 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
5 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
6 investigation.

7 123. The Manufacturer Defendants were able to influence AAPM through both their
8 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

9 124. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
10 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
11 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
12 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
13 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
14 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

15 125. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
16 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
17 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
18 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
19 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
20 practices, but they also are cited throughout the scientific literature and referenced by third-party
21 payors in determining whether they should cover treatments for specific indications.
22 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
23 guidelines with doctors during individual sales visits.

24 126. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
25 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,

26
27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
 2 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 3 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 4 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 5 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 6 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 7 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 8 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 9 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 10 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 11 disseminated in Costa Mesa during the relevant time period, are still available online, and were
 12 often reprinted in the Journal of Pain, which is the official journal of the American Pain Society.
 13 The Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS Guidelines
 14 without disclosing the lack of evidence to support their conclusions or the Manufacturer
 15 Defendants’ financial support to members of the panel.

16 127. On information and belief, the Manufacturer Defendants combined their efforts
 17 through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised
 18 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 19 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 20 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 21 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 22 worked to address a lack of coordination among its members and develop cohesive industry
 23 messaging.

24 128. On information and belief, through Front Groups and KOLs, the Manufacturer
 25 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 26 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 27

28 ²⁹ *Id.*

1 addiction.

2 129. Through these means, and likely others still concealed, the Manufacturer
3 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
4 opioid use.

5 **C. The Manufacturer Defendants' Statements about the Safety of Opioids Were**
6 **Patently False**

7 130. To convince doctors and patients that opioids carry a low risk of addiction,
8 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid
9 use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC
10 conclusively debunked.

11 131. These misrepresentations reinforced each other and created the dangerously
12 misleading impressions, among others, that: (a) starting patients on opioids was low-risk because
13 most patients would not become addicted, and because those who were at greatest risk of addiction
14 could be readily identified and managed; (b) patients who displayed signs of addiction probably
15 were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher
16 opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs,
17 do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are
18 inherently less addictive.

19 132. Some examples of these false and misleading claims that were made by, are
20 continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- 21 a. Actavis's predecessor caused a patient education brochure, Managing Chronic
22 Back Pain, to be distributed beginning in 2003 that admitted that opioid
23 addiction is possible, but falsely claimed that it is "less likely if you have never
24 had an addiction problem." Based on Actavis's acquisition of its predecessor's
25 marketing materials along with the rights to Kadian, it appears that Actavis
26 continued to use this brochure in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
28 People Living with Pain (2007), which suggests that addiction is rare and
limited to extreme cases of unauthorized dose escalations, obtaining
duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Costa Mesa, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

133. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

134. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

accessed December 19, 2017).

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

135. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

136. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

137. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

138. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

1 criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its
 2 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that
 3 patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG
 4 found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not
 5 to “make statements that ... opioids generally are non-addictive” or “that most patients who take
 6 opioids do not become addicted” in New York. This prohibition did not extend to California.

7 139. The Manufacturer Defendants falsely instructed doctors and patients that the signs
 8 of addiction are actually signs of undertreated pain and should be treated by prescribing more
 9 opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined
 10 by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and
 11 Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some
 12 illustrative examples of these deceptive claims that were made by, and are continuing to be made
 13 by Defendants are described below:

- 14 a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing*
 15 (2007), which taught that behaviors such as “requesting drugs by name,”
 16 “demanding or manipulative behavior,” seeing more than one doctor to obtain
 17 opioids, and hoarding, are all signs of pseudoaddiction, rather than true
 18 addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- 19 b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk*
 20 *Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient
 21 behaviors that may occur when pain is *under-treated* . . . Pseudoaddiction is
 22 different from true addiction because such behaviors can be resolved with
 23 effective pain management.”
- 24 c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program
 25 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
 26 Maximizing Analgesia,” which, upon information and belief, promoted
 27 pseudoaddiction by teaching that a patient’s aberrant behavior was the result of
 28 untreated pain. Endo appears to have substantially controlled NIPC by funding
 NIPC projects; developing, specifying, and reviewing content; and distributing
 NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which, upon information and belief, described pseudoaddiction as a
 concept that “emerged in the literature” to describe the inaccurate

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

1 interpretation of [drug- seeking behaviors] in patients who have pain that has
2 not been effectively treated.”

- 3 e. Upon information and belief, Purdue sponsored a CME program titled “Path of
4 the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in
5 2011. In a role play, a chronic pain patient with a history of drug abuse tells his
6 doctor that he is taking twice as many hydrocodone pills as directed. The
7 narrator notes that because of pseudoaddiction, the doctor should not assume
8 the patient is addicted even if he persistently asks for a specific drug, seems
9 desperate, hoards medicine, or “overindulges in unapproved escalating doses.”
10 The doctor treats this patient by prescribing a high-dose, long acting opioid.
11
12 f. Details for Purdue have directed doctors and their medical staffs in California,
13 including in Costa Mesa, to PartnersAgainstPain.com, which contained false
14 and misleading materials describing pseudoaddiction.
15
16 g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for
17 People Living with Pain (2007), which states: “Pseudo-addiction describes
18 patient behaviors that may occur when pain is undertreated...Pseudo-addiction
19 can be distinguished from true addiction in that this behavior ceases when pain
20 is effectively treated.”

21 **Deceptive Claims of Pseudoaddiction**

22 140. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects
23 pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not
24 experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience
25 clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with
26 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order
27 to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because
28 the patient is “not receiving a clear benefit.”

141. In connection with its 2016 settlement with the NY AG, Endo was forced to admit
that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he
pseudoaddiction concept has never been empirically validated and in fact has been abandoned by
some of its proponents” and reported that despite the fact that Endo trained its sales representative
to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk
Management testified to [the NY AG] that he was not aware of any research validating the
‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction

1 and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the
2 term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement
3 with respect to California.

4 142. The Manufacturer Defendants also falsely instructed doctors and patients that
5 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
6 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
7 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
8 general practitioners and family doctors who lack the time and expertise to closely manage higher-
9 risk patients on opioids. The Manufacturer Defendants’ misrepresentations made these doctors feel
10 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
11 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
12 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 13 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
14 *Family Practice* written by a doctor who became a member of Endo’s speakers
15 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
16 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
17 tools, claiming that patients at high risk of addiction could safely receive
18 chronic opioid therapy using a “maximally structured approach” involving
19 toxicology screens and pill counts.
- 20 b. On information and belief, Purdue sponsored a November 2011 webinar,
21 *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed
22 that screening tools, urine tests, and patient agreements prevent “overuse of
23 prescriptions” and “overdose deaths.”
- 24 c. On information and belief, as recently as 2015, Purdue has represented in
25 scientific conferences that “bad apple” patients – and not opioids – are the
26 source of the addiction crisis and that once those “bad apples” are identified,
27 doctors can safely prescribe opioids without causing addiction.
- 28 d. On information and belief, detailers for the Manufacturer Defendants have
touted and continue to tout to doctors in California, including Costa Mesa the
reliability and effectiveness of screening or monitoring patients as a tool for
managing opioid abuse and addiction.

143. Once again, the 2016 CDC Guideline confirms that these types of statements were
false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk

³⁷ See *supra* note 35, at 7.

1 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
2 widely believed by doctors to detect and deter abuse—“for improving outcomes related to
3 overdose, addiction, abuse, or misuse.” As a result, the 2016 CDC Guideline recognizes that
4 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
5 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
6 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

7 144. To underplay the risk and impact of addiction and make doctors feel more
8 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
9 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
10 failed to disclose the increased difficulty of stopping opioids after long-term use.

11 145. For example, on information and belief, a 2011 non-credit educational program
12 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
13 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

14 146. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
15 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
16 by gradually decreasing the dose of medication during discontinuation” without mentioning any
17 hardships that might occur.³⁸ This publication was available on APF’s website until the
18 organization dissolved in May 2012.

19 147. Detailers for Janssen have told and continue to tell doctors in California, including
20 Costa Mesa, that their patients would not experience withdrawal if they stopped using opioids.

21 **Deceptive Minimization of Opioid Withdrawal**

22 148. The Manufacturer Defendants also deceptively minimized the significant symptoms
23 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
24 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
25 understated the difficulty of tapering, particularly after long-term opioid use.

26 149. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline

27
28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

1 recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]”
 2 to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,”
 3 because “physical dependence on opioids is an expected physiologic response in patients exposed
 4 to opioids for *more than a few days*.” (Emphasis added.) The 2016 CDC Guideline states that
 5 “more than a few days of exposure to opioids significantly increases hazards” and “each day of
 6 unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The
 7 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years
 8 on high dosages because of physical and psychological dependence” and highlights the difficulties,
 9 including the need to carefully identify “a taper slow enough to minimize symptoms and signs of
 10 opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The
 11 CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of
 12 different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

13 **Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk**

14 150. The Manufacturer Defendants also falsely claimed that doctors and patients could
 15 increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to
 16 patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer
 17 Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this
 18 misrepresentation, doctors would have abandoned treatment when patients built up tolerance and
 19 lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that
 20 were made by, and are continuing to be made by Defendants, are described below:

- 21 a. On information and belief, Actavis’s predecessor created a patient brochure for
 22 Kadian in 2007 that stated, “Over time, your body may become tolerant of
 23 your current dose. You may require a dose adjustment to get the right amount
 24 of pain relief. This is not addiction.” Upon information and belief, based on
 25 Actavis’ acquisition of its predecessor’s marketing materials along with the
 26 rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- 27 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for*
 28 *People Living with Pain* (2007), which claims that some patients “need” a
 larger dose of an opioid, regardless of the dose currently prescribed. The guide

1 stated that opioids have “no ceiling dose” and are therefore the most
2 appropriate treatment for severe pain. This guide is still available online.³⁹

- 3 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
4 belief, claimed in 2009 that opioid dosages may be increased until “you are on
5 the right dose of medication for your pain.”
- 6 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your
7 Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120),
8 on Endo’s website. In Q&A format, it asked “If I take the opioid now, will it
9 work later when I really need it?” The response is, “The dose can be
10 increased... You won’t ‘run out’ of pain relief.”⁴⁰
- 11 e. Janssen, on information and belief, sponsored a patient education guide
12 entitled *Finding Relief: Pain Management for Older Adults* (2009), which was
13 distributed by its sales force. This guide listed dosage limitations as
14 “disadvantages” of other pain medicines but omitted any discussion of risks of
15 increased opioid dosages.
- 16 f. On information and belief, through March 2015, Purdue’s *In the Face of Pain*
17 website promoted the notion that if a patient’s doctor does not prescribe what,
18 in the patient’s view, is a sufficient dosage of opioids, he or she should find
19 another doctor who will.
- 20 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its
21 Management*, which taught that dosage escalations are “sometimes necessary,”
22 even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- 23 h. In 2007, Purdue sponsored a CME entitled “Overview of Management
24 Options” that was available for CME credit. The CME was edited by a KOL
25 and taught that NSAIDs and other drugs, but not opioids, are unsafe at high
26 dosages.
- 27 i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing
28 opioids, the Front Group APF and others argued to the United States Fourth
Circuit Court of Appeals that “there is no ‘ceiling dose’” for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug
Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue’s detailers have told doctors in California,
including in Costa Mesa that they should increase the dose of OxyContin,
rather than the frequency of use, to address early failure.

151. These claims conflict with the scientific evidence, as confirmed by the FDA and

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
accessed December 19, 2017).

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid
Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir.
Sept. 8, 2005).

1 CDC. As the CDC explained in its 2016 Guideline, the “[b]enefits of high-dose opioids for chronic
2 pain are not established” while the “risks for serious harms related to opioid therapy increase at
3 higher opioid dosage.” More specifically, the CDC explained that “there is now an established body
4 of scientific evidence showing that overdose risk is increased at higher opioid dosages.” The CDC
5 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
6 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
7 morphine milligram equivalents per day.

8 152. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
9 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
10 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
11 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
12 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
13 opioid-related overdose were initially prescribed opioids for chronic pain.

14 **Deceptive Advertising of Abuse Deterrent Opioids**

15 153. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
16 properties of some of their opioid formulations also has created false impressions that these opioids
17 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
18 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
19 addictive.

20 154. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
21 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
22 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
23 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
24 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
25 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
26 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
27 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
28 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term

1 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
2 Director of the CDC, has further reported that his staff could not find “any evidence showing the
3 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

4 155. Because of these significant limitations on AD opioids, as well as the heightened
5 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
6 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
7 be truthful and not misleading (based on a product’s labeling), and supported by sound science
8 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
9 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

10 156. Despite this lack of evidence, the Manufacturer Defendants have made and continue
11 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
12 to prevent or reduce abuse and addiction and the safety of these formulations.

13 157. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
14 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Opana
15 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was **no** evidence that
16 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
17 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
18 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
19 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
20 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
21 including doctors in Costa Mesa, that Opana ER is harder to abuse and given demonstrations to
22 nurse practitioners about Opana ER’s purported abuse deterrent properties.

23
24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
26 [push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

27 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
28 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou-](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm)
[ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

158. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those statements to be false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

159. Because Orpana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on June 8, 2017, and requested that Endo withdraw Opana ER from the market.

160. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-called abuse deterrent properties of Purdue’s opioid products as a primary selling point to differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral abuse or misuse, and that its abuse deterrent properties can be defeated.

161. These statements and omissions by Purdue are false and misleading, and conflict with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD opioids prevent or reduce abuse, misuse, or diversion.

162. Purdue knew and should have known that reformulated OxyContin is not better at

1 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
 2 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral
 3 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 4 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 5 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 6 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 7 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 8 being abused in large numbers.⁴⁶

9 163. Testimony in litigation against Purdue and other evidence indicates that Purdue
 10 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 11 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 12 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 13 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 14 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 15 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 16 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 17 opioid products.

18 164. The development, marketing, and sale of AD opioids is a continuation of the
 19 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 20 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 21 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 22 expensive than other opioid products even though they provide little or no additional benefit in the
 23 prevention of opioid abuse.

24 165. These false and misleading claims about the abuse deterrent properties of their
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 430.

27 ⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose*
 28 *epidemic*, Business Insider (Mar. 14, 2016), available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed December 20, 2017).

1 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 2 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 3 believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its
 4 earlier sins (even though its true motive was to preserve the profits it otherwise would have lost
 5 when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before
 6 its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw
 7 its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are
 8 falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions
 9 and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these
 10 opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe
 11 more AD opioids, which are far more expensive than other opioid products even though they
 12 provide little or no additional benefit in the prevention of opioid abuse.

13 166. These numerous, longstanding misrepresentations of the risks of long-term opioid
 14 use spread by Defendants successfully convinced doctors and patients to discount those risks.

15 **D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid**
 16 **Therapy**

17 167. To convince doctors and patients that opioids should be used to treat chronic pain,
 18 the Manufacturer Defendants also had to persuade them that there was significant upside to long-
 19 term opioid use.

20 168. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine
 21 long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found
 22 that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 23 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 24 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 25 and less harmful than long-term opioid use.

26 169. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled
 27 studies of opioids use longer than 12 weeks.”

28 170. Despite this, the Manufacturer Defendants falsely and misleadingly touted the

benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these false and misleading claims, but they have continued to make them today.

171. For example, the Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. On information and belief, Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. On information and belief, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"
- d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.
- e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by Cephalon and Purdue, counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational programs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen

claiming that opioids allowed a patient to “continue to function.” This video is still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.” The Policymaker’s Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue’s Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue’s opioids, to chronic pain patients’ “quality of life,” and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue’s, Endo’s, Teva’s and Janssen’s sales representatives have conveyed and continue to convey to prescribers in California, including in Costa Mesa, the message that opioids will improve patient function.

172. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that “there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely.” (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. “No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later”
- b. “Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy.”
- c. “[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia.”

173. The CDC also noted that the risks of addiction and death “can cause distress and inability to fulfill major role obligations.” As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

174. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

175. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids,

⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm'n's, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at <http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/ucm259240.htm> (last accessed December 20, 2017).

⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

2 176. In addition, Purdue has misleadingly promoted OxyContin as being unique among
3 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
4 believes that Purdue's detailers have told prescribers in California within the last two years that
5 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
6 fact that Purdue has known at all times relevant to this action. Upon information and belief,
7 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
8 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
12 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
13 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the end of
15 each dosing period drives them to take more OxyContin before the next dosing period begins,
16 quickly increasing the amount of drug they are taking and spurring growing dependence.

17 177. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
18 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
19 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
20 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
21 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
22 Fentora for the treatment of chronic pain because of the potential harm.

23 178. Despite this, Plaintiff is informed and believes that Cephalon conducted and
24 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
25 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this

26 _____
27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
2017).

1 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
2 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
3 effective for treating non-cancer, chronic pain.

4 179. Cephalon's deceptive marketing gave doctors and patients the false impression that
5 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
6 by the FDA for such uses. For example:

- 7 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
8 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
9 News in 2009. The CME instructed doctors that "[c]linically, broad
10 classification of pain syndromes as either cancer- or non-cancer-related has
11 limited utility" and recommended Actiq and Fentora for patients with chronic
12 pain.
- 13 b. Upon information and belief, Cephalon's sales representatives set up hundreds
14 of speaker programs for doctors, including many non-oncologists, which
15 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 16 c. In December 2011, Cephalon widely disseminated a journal supplement
17 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
18 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
19 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
20 and Pain Medicine News – three publications that are sent to thousands of
21 anesthesiologists and other medical professionals. The Special Report openly
22 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

23 180. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
24 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
25 representatives have told doctors that in California that they will no longer be asked to give paid
26 talks unless they increase their prescribing of Purdue's drugs.

27 181. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
28 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

182. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of

1 thousands of doctors in California and could identify California doctors who displayed red flags
2 for diversion, including doctors whose waiting rooms were overcrowded, parking lots had
3 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
4 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
5 prescribing its drugs.

6 183. Incredibly, rather than report these doctors to state medical boards or law
7 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
8 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
9 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
10 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
11 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
12 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
13 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
14 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
15 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
16 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
17 so, Purdue protected its own profits at the expense of public health and safety.

18 184. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
19 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
20 those prescribers even after they were placed on a “no-call” list.

21 185. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
22 Services, said in a Los Angeles Times article, “Any drug company that has information about
23 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
24 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
25 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
26 Purdue continues to profit from the prescriptions by such prolific prescribers.

27 186. Like Purdue, Endo has been cited for its failure to set up an effective system for
28 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY

1 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
2 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers
3 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
4 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
5 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
6 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
7 could have recognized potential signs of diversion and reported those prescribers but failed to do
8 so.

9 187. The Manufacturer Defendants made, promoted, and profited from their
10 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
11 that their misrepresentations were false and misleading. The history of opioids, as well as research
12 and clinical experience over the last 20 years, established that opioids were highly addictive and
13 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
14 access to scientific studies, detailed prescription data, and reports of adverse events, including
15 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
16 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
17 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
18 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
19 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
20 same misrepresentations described in this Complaint.

21 188. On information and belief, the Manufacturer Defendants coordinated their
22 messaging through national and regional sales and speaker trainings and coordinated
23 advertisements and marketing materials.

24 189. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
25 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
26 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
27 therapy by funding and working through third parties like Front Groups and KOLs. The
28 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and

1 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
2 Defendants' false and misleading statements about the risks and benefits of long-term opioid use
3 for chronic pain.

4 190. Manufacturer Defendants also never disclosed their role in shaping, editing, and
5 approving the content of information and materials disseminated by these third parties.
6 Manufacturer Defendants exerted considerable influence on these promotional and "educational"
7 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
8 companies that were not, and have not yet become, public. For example, painknowledge.org, which
9 is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as
10 Purdue and Janssen, ran similar websites that masked their own direct role.

11 191. Finally, the Manufacturer Defendants manipulated their promotional materials and
12 the scientific literature to make it appear that the information and materials disseminated by third
13 parties were accurate, truthful, and supported by objective evidence when they were not. The
14 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
15 evidence for propositions the studies did not support. The lack of support for the Manufacturer
16 Defendants' deceptive messages was not apparent to medical professionals who relied upon them
17 in making treatment decisions, nor could it have been detected by Costa Mesa.

18 192. The Manufacturer Defendants' efforts to artificially increase the number of opioid
19 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
20 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and
21 has increased in parallel with [opioid] overdoses."⁵¹ Many abusers start with legitimate
22 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
23 for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent
24 opioid-related morbidity."⁵² Accordingly, the Manufacturer Defendants' false and misleading
25 statements directly caused the current opioid epidemic. The Manufacturer Defendants'

26
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

28 ⁵² *Id.*

1 misrepresentations deceived and continue to deceive doctors and patients in California, including
2 in Costa Mesa, about the risks and benefits of long-term opioid use. California doctors confirm this.
3 Studies also reveal that many doctors and patients are not aware of or do not understand these risks
4 and benefits. Indeed, patients often report that they were not warned they might become addicted
5 to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid
6 patients found that 4 out of 10 were not told opioids were potentially addictive. Plaintiff is informed
7 and believes that California residents were never told that they might become addicted to opioids
8 when they started taking them, were told that they could easily stop using opioids, or were told that
9 the opioids they were prescribed were less addictive than other opioids.

10 193. Numerous doctors and substance abuse counselors in California note that many of
11 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
12 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
13 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
14 for opioid addiction.

15 194. The Manufacturer Defendants knew and should have known that their
16 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
17 when they made them.

18 195. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
19 properties of their opioids caused and continue to cause doctors in California, including doctors in
20 Costa Mesa, to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis,
21 and fibromyalgia, rather than prescribing less addictive medications. Absent Manufacturers
22 Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids
23 to as many patients, and there would not have been as many opioids available for misuse and abuse
24 or as much demand for those opioids.

25 196. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
26 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
27 California, including in Costa Mesa. Opioids are the most common means of treatment for chronic
28 pain; 20% of office visits now include the prescription of an opioid, and 4 million Americans per

1 year are prescribed a long-acting opioid.

2 197. In California, including Costa Mesa, Manufacturer Defendants' deceptive
3 marketing of the abuse-deterrent properties of their opioids during the past few years has been
4 particularly effective. For example, one survey reports that pain specialists were more likely to
5 recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically
6 because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent
7 properties were using more of it than those who did not know it was an AD opioid. Although sales
8 of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold
9 in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or
10 approximately 25% in opioid sales revenue in 2015).

11 198. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
12 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
13 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
14 that spending had tripled to \$288 million.

15 **E. All Defendants Created an Illicit Market for Opioids**

16 199. In addition to the allegations above, all Defendants played a role in the creation of
17 an illicit market for prescription opioids, further fueling the opioid epidemic.

18 200. Defendants' distribution of opioids was driven by national policies, coordination,
19 plans, and procedures that were the same in California as they were across the rest of the United
20 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
21 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
22 vastly increasing their respective profits and revenues by exponentially expanding a market that the
23 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
24 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
25 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
26 possible financial return.

27 201. Each participant in the supply chain shares the responsibility for controlling the
28 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of

1 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
2 distribution or use to an illegitimate channel of distribution or use.

3 202. Diversion can occur at any point in the opioid supply chain.

4 203. For example, diversion can occur at the wholesale level of distribution when
5 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
6 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
7 size, orders that are disproportionately large in comparison to the population of a community served
8 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

9 204. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
10 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
11 usual course of practice. Some of the signs that a prescription may have been issued for an
12 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
13 different doctors (known as doctor shopping), when they travel great distances between the doctor
14 or their residence and the pharmacy to get the prescription filled, when they present multiple
15 prescriptions for the largest dose of more than one controlled substance, or when there are other
16 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
17 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
18 to treat a legitimate medical condition.

19 205. Diversion occurs through the use of stolen or forged prescriptions or the sale of
20 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
21 Opioids can also be diverted when stolen by employees or others.

22 206. Opioid diversion occurs at an alarming rate in the United States.

23 207. Each participant in the supply chain, including each Defendant, has a common law
24 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
25 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
26 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
27 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

28 208. Defendants, and not Plaintiff, controlled the manufacture, marketing, and

1 distribution of prescription opioids within Plaintiff's boundaries. As such, Defendants were in the
2 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.
3 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

4 209. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
5 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
6 duty in their misleading and inaccurate promotion of prescription opioids.

7 210. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
8 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
9 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
10 suspicious orders.

11 **211.** In addition to their common law duties, Defendants possess duties under California
12 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
13 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
14 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
15 4164 and 4169.1.

16 212. Separately, Defendants also are subject to federal statutory requirements of the
17 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
18 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
19 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
20 U.S.C.C.A.N. 4566, 4572.

21 213. Defendants' repeated and prolific violations of these requirements show that they
22 have failed to meet the relevant standard of conduct that society expects of them: the duty to
23 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
24 willful disregard for Costa Mesa and the people therein.

25 214. California law requires Defendants to report suspicious orders of dangerous drugs
26 subject to abuse, and to develop and maintain systems to detect and report such activity. This
27 framework acts as a system of checks and balances from the manufacturing level through delivery
28 of the controlled substance to the patient or ultimate user.

1 215. Thus, all opioid distributors are required to maintain effective controls against
2 opioid diversion. They are required to create and use a system to identify and report to the California
3 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
4 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
5 and/or orders of unusual frequency. To comply with these requirements, distributors must know
6 their customers, must conduct due diligence, must report suspicious orders, and must terminate
7 orders if there are indications of diversion.

8 216. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
9 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
10 their obligations under the CSA.

11 217. Under the CSA, anyone authorized to handle controlled substances must track
12 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
13 automated drug reporting system that records and monitors the flow of Schedule II controlled
14 substances from the point of manufacture through distribution to the point of sale. ARCOS
15 accumulates data on distributors' controlled substances and transactions, which are then used to
16 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
17 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
18 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
19 and current record of each substance manufactured, imported, received, sold, delivered, exported,
20 or otherwise disposed of.

21 218. Plaintiff does not bring causes of action based on violations of federal statutes and
22 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
23 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
24 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
25 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
26 prescription opioids.

1 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
2 **Opioids to Costa Mesa Through Illicit Channels**

3 219. The Distributor Defendants have been and continue to be well-aware of problems
4 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance
5 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
6 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
7 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
8 that the DEA also provides distributors with data on controlled substance distribution patterns and
9 trends, including data on the volume and frequency of orders and the percentage of controlled
10 versus non-controlled purchases. The distributors are also given case studies, legal findings against
11 other registrants, and ARCOS profiles of their customers whose previous purchases may have
12 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
13 Defendants should look for in order to identify potential diversion.

14 220. Since 2007, the DEA has hosted at least five conferences to provide registrants with
15 updated information about diversion trends and regulatory changes that affect the drug supply
16 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
17 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
18 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
19 also request clarification on DEA policies, procedures, and interpretations of the CSA and
20 implementing regulations.

21 221. Since 2008, the DEA also has participated in numerous meetings and events with
22 the legacy Healthcare Distribution Management Association (HDMA), now known as the
23 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
24 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
25 guidance to the association concerning suspicious order monitoring, and the association has
26 published guidance documents for its members on suspicious order monitoring, reporting
27 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
28 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”

1 (2008).)

2 222. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
3 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
4 and the responsibilities and obligations of registrants to prevent diversion.

5 223. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to
6 DEA registrants providing guidance and reinforcing the legal requirements outlined in the
7 September 2006 correspondence. The December 2007 letter reminded registrants that suspicious
8 orders must be reported when discovered and monthly transaction reports of excessive purchases
9 did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants
10 that they must perform an independent analysis of a suspicious order prior to the sale to determine
11 if controlled substances would likely be diverted, and that filing a suspicious order and then
12 completing the sale does not absolve the registrant from legal responsibility.

13 224. Distributor Defendants' own industry group, the Healthcare Distribution
14 Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious
15 Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each
16 member of the supply chain in distributing controlled substances. These industry guidelines stated:
17 "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due
18 diligence in order to help support the security of controlled substances they deliver to their
19 customers."

20 225. Opioid distributors have admitted to the magnitude of the problem and, at least
21 superficially, their legal responsibility to prevent diversion. They have made statements assuring
22 the public they supposedly are undertaking a duty to curb the opioid epidemic.

23 226. For example, a Cardinal executive recently claimed that it uses "advanced analytics"
24 to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as
25 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

26 227. McKesson has publicly stated that it has a "best-in-class controlled substance
27 monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about
28 curbing the opioid epidemic in our country."

228. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

229. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.⁵³

230. Their misconduct and negligent failure to prevent diversion is demonstrated by the fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

- a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters." McKesson was fined \$150,000,000;⁵⁵
- b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion;
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 231. Although distributors have been penalized by law enforcement authorities, these
2 penalties have not changed their conduct. They pay fines as a cost of doing business in an industry
3 that generates billions of dollars in revenue and profit.

4 232. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid
5 diversion created an enormous black market for prescription opioids, which market extended to
6 Costa Mesa and its residents. Each Distributor Defendant knew or should have known that the
7 opioids reaching Costa Mesa were not being consumed for medical purposes and that the amount
8 of opioids flowing to Costa Mesa was far in excess of what could be consumed for medically
9 necessary purposes.

10 233. The Distributor Defendants negligently or intentionally failed to adequately control
11 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
12 substances would have anticipated the danger of opioid diversion and protected against it by, for
13 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
14 greater oversight, security, and control of supply channels; (c) looking more closely at the
15 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
16 amounts greater than the populations in those areas would warrant; (d) investigating demographic
17 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
18 Costa Mesa; (e) providing information to pharmacies and retailers about opioid diversion; and (f)
19 in general, simply following applicable statutes, regulations, professional standards, and guidance
20 from government agencies and using a little bit of common sense.

21 234. On information and belief, the Distributor Defendants made little to no effort to visit
22 the pharmacies servicing the areas around Costa Mesa to perform due diligence inspections to
23 ensure that the controlled substances the Distributor Defendants had furnished were not being
24 diverted to illegal uses.

25 235. On information and belief, the compensation the Distributor Defendants provided
26 to certain of their employees was affected, in part, by the volume of their sales of opioids to
27 pharmacies and other facilities servicing the areas around Costa Mesa, thus improperly creating
28 incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid

1 abuse.

2 236. It was reasonably foreseeable to the Distributor Defendants that their conduct in
3 flooding the market in and around Costa Mesa with highly addictive opioids would allow opioids
4 to fall into the hands of children, addicts, criminals, and other unintended users.

5 237. It was reasonably foreseeable to the Distributor Defendants that, when unintended
6 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
7 and death. It was also reasonably foreseeable that many of these injuries would be suffered by Costa
8 Mesa residents, and that the costs of these injuries would be borne by Costa Mesa.

9 238. The Distributor Defendants knew or should have known that the opioids being
10 diverted from their supply chains would contribute to the opioid epidemic faced by Costa Mesa,
11 and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
12 addiction, demand, illegal transactions, economic ruin, and human tragedy.

13 239. The Distributor Defendants were aware of widespread prescription opioid abuse in
14 and around Costa Mesa, but, on information and belief, they nevertheless persisted in a pattern of
15 distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
16 with such frequency that they knew or should have known these commonly abused controlled
17 substances were not being prescribed and consumed for legitimate medical purposes.

18 240. The use of opioids by Costa Mesa residents who were addicted or who did not have
19 a medically necessary purpose could not have occurred without the knowing cooperation,
20 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
21 Defendants adhered to effective controls to guard against diversion, Costa Mesa and its residents
22 would have avoided significant injury.

23 241. The Distributor Defendants made substantial profits over the years based on the
24 diversion of opioids into Costa Mesa. The Distributor Defendants knew that Costa Mesa would be
25 unjustly forced to bear the costs of these injuries and damages.

26 242. The Distributor Defendants' intentional distribution of excessive amounts of
27 prescription opioids showed an intentional or reckless disregard for the safety of Costa Mesa and
28 its residents. Their conduct poses a continuing threat to the health, safety, and welfare of Costa

1 Mesa.

2 243. The state laws at issue here are public safety laws.

3 244. The Distributor Defendants' violations constitute prima facie evidence of
4 negligence under state law.

5 **2. The Manufacturer Defendants Negligently Failed to Control the Flow**
6 **of Opioids to Costa Mesa Through Illicit Channels**

7 245. The same legal duties to prevent diversion, and to monitor, report, and prevent
8 suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants
9 were also legally required of the Manufacturer Defendants under California law.

10 246. In addition to a common law duty to exercise reasonable care in the promotion and
11 marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous
12 drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts
13 determined by the Board. *See* 16 CCR 1782.

14 247. On information and belief, for over a decade the Manufacturer Defendants have
15 been able to track the distribution and prescribing of their opioids down to the retail and prescriber
16 level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of
17 doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those
18 red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the
19 Manufacturer Defendants breached their duties under state law.

20 248. The Manufacturer Defendants had access to and possession of the information
21 necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The
22 Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors.
23 A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the
24 manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's
25 product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer
26 and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume
27 and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the
28 volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer

1 Defendants built receipt of this information into the payment structure for the opioids provided to
2 the opioid distributors.

3 249. The Manufacturer Defendants' actions and omission in failing to effectively prevent
4 diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful
5 diversion of opioids into Costa Mesa.

6 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

7 250. As the demand for prescription opioids grew, fueled by their potency and purity,
8 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
9 traveling across state, city, and county lines in a variety of ways.

10 251. First, prescriptions written in one state would, under some circumstances, be filled
11 in a different state. But even more significantly, individuals transported opioids from one
12 jurisdiction specifically to sell them in another.

13 252. When authorities in one state cracked down on opioid suppliers, out-of-state
14 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
15 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
16 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
17 practice became so common that authorities dubbed these individuals "prescription tourists."

18 253. The facts surrounding numerous criminal prosecutions illustrate this common
19 practice. For example, in May 2018 a mother-son crime duo based out of New Jersey was caught
20 flying to California in attempts to obtain additional sources of supply for their drug operation which
21 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

22 254. In another example, a man from Warren County, Ohio, who was sentenced to four
23 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
24 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
25 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a

26 _____
27 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

28 ⁵⁹ Andrew Welsh-Huggins, Associated Press, '*Prescription Tourists*' Thwart States' Crackdown on Illegal Sale of Painkillers, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-

1 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
2 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader
3 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
4 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
5 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
6 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

7 255. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
8 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
9 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
10 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
11 customers were from other states.⁶³

12 256. In yet another case, defendants who operated a pill mill in south Florida within
13 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
14 transported oxycodone back to the area for both use and distribution by local drug trafficking
15 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
16 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
17 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
18 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
19 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
20

21 painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

22 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
<http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last
23 accessed July 25, 2018).

24 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
available at [http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html)
[sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html](http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html) (last accessed July 25, 2018).

25 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead*
Guilty to Operating a “Pill Mill” in Lilburn, Georgia (May 14, 2015), available at
26 <https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last
accessed July 25, 2018).

27 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists*
Convicted for Illegally Dispensing to Patients of a Pill Mill (Mar. 29, 2017), available at
28 [https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill)
[patients-pill-mill](https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill) (last accessed July 25, 2018).

1 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
 2 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
 3 Kentucky residents.”⁶⁵

4 257. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so
 5 well traveled that it became known as the Blue Highway, a reference to the color of the 30mg
 6 Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with
 7 certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars
 8 just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple
 9 pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid
 10 the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads
 11 altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so
 12 popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

13 258. While the I-75 corridor was well utilized, prescription tourists also came from other
 14 states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill
 15 mills come from as far away as Arizona and Nebraska.⁷⁰

16 259. Similar pipelines developed in other regions of the country. For example, the I-95
 17 corridor was another transport route for prescription pills. As the director of the Maine Drug
 18 Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida,
 19 Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid
 20

21 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

22 ⁶⁵ *Id.* at 861.

23 ⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America’s*
 24 *Deadliest Drug Epidemic* 171 (2016).

25 ⁶⁷ *Id.* at 172

26 ⁶⁸ *Id.* at 171

27 ⁶⁹ *Id.*

28 ⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal
 Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71>
 (last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*,
 Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running>
 (last accessed July 25, 2018)

1 epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia,
2 Ohio, and Kentucky.

3 260. Along the west coast, over a million pills were transported from the Lake Medical
4 pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²
5 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
6 Everett-based dealer who received the pills from southern California wore a diamond necklace in
7 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
8 OxyContin—connecting Los Angeles and Washington state.

9 261. Defendants certainly were aware, or should have been aware, that pill mills from
10 around the country were pushing its products. Defendants purchased nationwide, regional, state,
11 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
12 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
13 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
14 compute, and track their competitors' sales, and to compare and analyze market share information.

15 262. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
16 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
17 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
18 regarding competing drugs, and analyzed the market share of those drugs.

19 263. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
20 rewarded sales representatives who happened to have pill mills within their territories, enticing
21 those representatives to look the other way even when their in-person visits to such clinics should
22 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
23 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
24 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
25 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric

26
27 ⁷² Harriet Ryan et al., How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and
Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

28 ⁷³ *Id.*

1 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
2 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
3 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
4 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
5 inappropriately, such activity would continue regardless of whether we contacted the doctor or
6 not."⁷⁴

7 264. In another example, a Purdue sales manager informed her supervisors in 2009 about
8 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
9 sales representative "it was packed with a line out the door, with people who looked like gang
10 members," and that she felt "very certain that this an organized drug ring[.]"⁷⁵ She wrote, "This is
11 clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue
12 responded that while they were "considering all angles," it was "really up to [the wholesaler] to
13 make the report."⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
14 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
15 2010 to inform the authorities.

16 265. Abundant evidence, thus, establishes that prescription opioids migrated between
17 states, counties, and cities and that Defendants were aware of it. As a result, Defendants' public
18 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
19 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
20 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
21 prescription opioid pills were hard to get in one area, they migrated from another. The
22 manufacturers and distributors were fully aware of this phenomenon and profited from it.

23 266. Defendants each knew or should have known that opioid diversion and abuse was
24 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide

25 ⁷⁴ Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* 204, 289-399
26 (Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
28 *Addicts. What the Drugmaker Knew*, Los Angeles Time (July 10, 2016),
<http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

1 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
2 allowed to continue the unlawful diversion of opioids into Costa Mesa.

3 **G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the**
4 **Harm Alleged Herein and Substantial Damages**

5 267. As the Manufacturer Defendants' efforts to expand the market for opioids increased,
6 so have the rates of prescription and the sale of their products, as well as the rates of opioid-related
7 substance abuse, hospitalization, and death among Costa Mesa residents and across the nation.
8 Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of
9 opioids into communities like Costa Mesa, fueling the epidemic.

10 268. There is a "parallel relationship between the availability of prescription opioid
11 analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and
12 associated adverse outcomes."⁷⁷

13 269. Opioids are widely diverted and improperly used, and the widespread use of the
14 drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

15 270. The epidemic is "directly related to the increasingly widespread misuse of powerful
16 opioid pain medications."⁷⁹

17 271. The increased abuse of prescription opioids—along with growing sales—has
18 contributed to a large number of overdoses and deaths.

19 272. As shown above, the opioid epidemic has escalated in Costa Mesa with devastating
20 effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants'
21 increased distribution of opioids.

22 273. Because of the well-established relationship between the use of prescription opioids
23 and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to Costa
24 Mesa and areas from which opioids are being diverted to Costa Mesa, has caused the opioid
25 epidemic to include heroin addiction, abuse, and death.

26 _____
27 ⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N.
Eng. J. Med. 241 (2015).

28 ⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

1 274. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public
2 health and safety in Costa Mesa.

3 275. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and
4 safety in Costa Mesa.

5 276. Defendants repeatedly and purposefully breached their duties under state law, and
6 such breaches are direct and proximate causes of, and/or substantial factors leading to, the
7 widespread diversion of prescription opioids for nonmedical purposes in Costa Mesa.

8 277. The unlawful diversion of prescription opioids is a direct and proximate cause of,
9 and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction,
10 morbidity, and morality in Costa Mesa. This diversion and the resulting epidemic are direct causes
11 of foreseeable harms incurred by Costa Mesa and residents of Costa Mesa.

12 278. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past
13 and continuing, economic damages for which Costa Mesa seeks relief, as alleged herein. Costa
14 Mesa also seeks the means to abate the epidemic created by the Defendants.

15 279. Costa Mesa seeks economic damages from the Defendants as reimbursement for the
16 costs associated with past efforts to eliminate the hazards to public health and safety.

17 280. Costa Mesa seeks economic damages from the Defendants to pay for the costs to
18 permanently eliminate the hazards to public health and safety and abate the public nuisance.

19 281. Costa Mesa seeks economic damages from the Defendants to pay for the reduction
20 to tax revenues caused by the epidemic created by the Defendants.

21 282. To eliminate the hazard to public health and safety, and abate the public nuisance, a
22 "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

23 283. A comprehensive response to this crisis must focus on preventing new cases of
24 opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective
25 opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

26 _____
27 ⁸⁰ Rudd, *supra* note 51.

28 ⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at <https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and->

1 284. The community-based problems require community-based solutions that have been
2 limited by budgetary constraints.

3 285. Having profited enormously through the aggressive sale, misleading promotion, and
4 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
5 financial burdens their conduct has inflicted upon Costa Mesa.

6 286. The opioid epidemic still rages because the fines and suspensions imposed by the
7 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
8 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
9 registration numbers and when one facility is suspended, they simply ship from another facility.

10 287. The Defendants have abandoned their duties imposed by the law, taken advantage
11 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
12 Costa Mesa.

13 288. In the course of conduct described in this Complaint, Defendants have acted with
14 oppression, fraud, and malice, both actual and presumed.

15 **H. The Impact of Opioid Abuse on Costa Mesa**

16 289. Defendants' creation, through false and misleading advertising and a failure to
17 prevent diversion, of a virtually limitless opioid market has significantly harmed Costa Mesa and
18 resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
19 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
20 abused come, directly or indirectly, through doctors' prescriptions.

21 290. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
22 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
23 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
24 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
25 associated with the consumption of a counterfeit version of the prescription drug Norco
26 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has

27 _____
28 [effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf](https://www.cdph.ca/Programs/CID/DCDC/Pages/Effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf) (last accessed
January 8, 2018).

1 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
2 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
3 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further
4 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
5 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
6 concern. Meanwhile in Orange County, the 4,012 opioid overdoses between 2011 and 2015 resulted
7 in more than 20,000 hospital days. Over the same period, over 1,200 people died from opioid-
8 related overdoses, with 55% of those resulting from prescription opioids.

9 291. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
10 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
11 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
12 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
13 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

14 292. Even Costa Mesa's youngest residents bear the consequences of the opioid abuse
15 epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for drug
16 treatment services during pregnancy abused opioids. By 2012, opioids were the most commonly
17 abused substance by pregnant women, accounting for 38 percent of all drug treatment admissions.⁸⁴
18 Many Costa Mesa women have become addicted to prescription opioids and have used these drugs
19 during their pregnancies. As a result, many Costa Mesa infants suffer from opioid withdrawal and
20 Neonatal Abstinence Syndrome ("NAS").⁸⁵

21 _____
22 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
23 *year*, LA Times (Oct. 27, 2014), available at [http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html)
24 [prescription-hospital-er-20141026-story.html](http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html) (last accessed December 21, 2017).

25 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
26 *The Opioid Crisis in Indian Country*, at 37, available at
27 <https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
28 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US, 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at

293. The impact of NAS can be life-long. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require an emergency evacuation for care to save the infant's life. Such emergency transportation can cost thousands of dollars for each occurrence. Recently, emergency responders in Costa Mesa had to deliver life-saving treatment to a 9-month-old baby who had ingested fentanyl.

294. Many NAS infants have short-term and long-term developmental issues that prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and digestive issues; some are unable to attend full days of school. These disabilities follow these children through elementary school and beyond.

295. Many of the parents of these children continue to relapse into prescription opioid use and abuse. As a result, many of these children are placed in foster care or adopted.

296. Opioid addiction is now the primary reason that Californians seek substance abuse treatment, and admissions to drug treatment facilities in California more than doubled from 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one facility in northern California, up to 90% – started on legal opioid prescriptions.

297. The explosion in opioid prescriptions and use caused by Defendants has led to a public health crisis in California. California faces skyrocketing opioid addiction and opioid-related overdoses and deaths as well as devastating social and economic consequences. This public health crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]” and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each Defendant's deceptive marketing and distribution scheme are catastrophic and are only getting worse.

298. There is little doubt that each Defendant's deceptive marketing and distribution scheme has precipitated this public health crisis in California, including Costa Mesa, by dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has

<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids
2 has created a population of patients physically and psychologically dependent on them (the
3 demand). And when those patients can no longer afford or legitimately obtain opioids, they often
4 turn to the street to buy prescription opioids or even heroin.

5 299. The effects of Defendants' deceptive marketing and distribution scheme has further
6 impacted Plaintiff in a foreseeable way such that Costa Mesa must devote increased resources to
7 the burden of the addicted homeless who commit drug and property crimes, to feed their addiction.
8 For example, tax dollars are required to maintain public safety of places where the addicted
9 homeless attempt to congregate, including parks, schools and public lands. Tax dollars are required
10 to fight the infectious diseases frequently carried by addicts, and particularly the addicted homeless.
11 Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant *Staphylococcus*
12 *aureus* (MRSA) are spread by opioid abuse.

13 300. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
14 have recruited addicts nationally with false and misleading promises of the medically supervised
15 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
16 effective rehabilitation available in beautiful California communities, including Costa Mesa. These
17 for-profit rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations
18 revealed that many have provided substandard care including use of physicians who have had their
19 license revoked, operating staffs which do not actually supervise patients, and facilities that do not
20 operate programs for addicts. Instead these facilities bring addicts to Costa Mesa, provide
21 substandard care as long as there are third party payments available, and then throw them out of
22 the facilities to be homeless. These addicts brought to Costa Mesa by the substandard rehab
23 industry, have further contributed to the public's burden by discharging addicted homeless into the
24 community who require further care and rehabilitation at the public's expense, and who commit
25 crimes in Costa Mesa in order to further feed their addiction. The manufacturer and distributor
26 Defendants were aware at all relevant times when they deceptively marketed their products as non-
27 addictive that such addiction would be highly difficult to overcome. Defendants knew or should
28 have known that municipalities, including Costa Mesa, would bear the burden of costs associated

1 with rehabilitation business of all types.

2 301. The role of Defendants' deceptive marketing and distribution scheme in causing this
3 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
4 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
5 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have
6 contributed to the severity of the current prescription drug abuse problem." And in August 2016,
7 the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy
8 marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids
9 are not addictive when prescribed for legitimate pain." California doctors, addiction treatment
10 specialists, and law enforcement and public health officials confirm that prescription opioids
11 lawfully prescribed by doctors have fueled this epidemic.

12 302. Absent each Defendant's deceptive marketing scheme and improper distribution,
13 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
14 the opioid epidemic that now exists would have been averted or much less severe.

15 303. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
16 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
17 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
18 only engaged in false advertising, they have also created or assisted in the creation of a public
19 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the present
20 is part of its deceptive marketing and distribution scheme and subjects that Defendant to liability
21 for public nuisance because there is no statute of limitations for a public nuisance claim. *See* Cal.
22 Civ. Code § 3490 ("No lapse of time can legalize a public nuisance, amounting to an actual
23 obstruction of public right"); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 ("the maintenance
24 of a public nuisance may not be defended on the ground of laches or the statute of limitations").

25 304. Accordingly, Defendants' conduct, both individually and collectively, has violated
26 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
27 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Costa Mesa does not seek to limit the
28 ability of doctors in California to prescribe opioids. Costa Mesa does not ask this Court to weigh

1 the risks and benefits of long-term opioid use. Instead, Costa Mesa seeks an order requiring
2 Defendants to cease their unlawful promotion and distribution of opioids, to correct their
3 misrepresentations, and to abate the public nuisance they have created. To redress and punish
4 Defendants' previous and current violations of law that cause and continue to cause harm to Costa
5 Mesa, Plaintiff seeks a judgment requiring Defendants to pay civil penalties, and any fees or costs
6 permitted under law.

7 305. By this action, Costa Mesa further seeks to recoup tax dollars spent already for the
8 consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and its
9 impact on this county and its communities, and to abate the opioid nuisance so Costa Mesa will not
10 be required to spend further taxpayer dollars on the epidemic and crisis wrought by Defendants'
11 wrongful conduct as alleged herein.

12 306. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
13 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
14 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
15 California spiked by 34% from 2011 to 2013.

16 307. Opioid abuse also contributes to a range of social problems including physical and
17 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
18 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
19 unemployment, and despair. More and more Costa Mesa resources are needed to combat these
20 problems. The prescription opioid crisis also diminishes Costa Mesa's available workforce,
21 decreases productivity, increases poverty, and requires greater governmental expenditures by Costa
22 Mesa.

23 308. The prescription opioid crisis has directly financially injured Costa Mesa. The crisis
24 has led to an increased demand for, *inter alia*, security services (such as police, EMS, detention),
25 higher insurance costs, child protective services, health and housing services, clean-up services,
26 and legal services. Costa Mesa has also had to hire additional staff and expend additional resources
27 to manage the demand.

28 309. Costa Mesa's medical services have seen an increase in opioid-related health

1 problems among Costa Mesa residents, including, but not limited to, infants born with opioid-
2 related medical conditions. This has resulted in increased demand and increased expenses.

3 310. Costa Mesa has also suffered substantial financial damages in the form of lost
4 productivity of Costa Mesa employees and residents, lost economic activity, lost reputation and
5 good will, and the lost opportunity for growth. These damages have been suffered and continue to
6 be suffered directly by Costa Mesa.

7 311. Many patients who become addicted to opioids will lose their jobs. Some will lose
8 their homes and their families. Some will get treatment and fewer will successfully complete it;
9 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
10 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
11 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
12 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
13 drug transactions; or dying from opioid-induced heart or neurological disease.

14 312. Costa Mesa also has suffered substantial financial damages in the form of lost taxes
15 paid by its residents and businesses as a result of lost earnings and productivity.

16 313. While the use of opioids has taken an enormous toll on Costa Mesa and its residents,
17 Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in
18 revenue for drug companies like the Defendants. Indeed, on information and belief, each Defendant
19 experienced a material increase in sales, revenue, and profits from the unlawful conduct described
20 above.

21 **I. The Statutes of Limitations Are Tolled and Defendants Are Estopped from**
22 **Asserting Statutes of Limitations As Defenses**

23 314. Defendants' conduct has continued from the early 1990s through today and remains
24 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
25 continuous injury. The damages have not occurred all at once but have continued to occur and have
26 increased as time progresses. The tort is not completed nor have all the damages been incurred until
27 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
28 public nuisance remains unabated.

1 315. Defendants are equitably estopped from relying upon a statute of limitations defense
2 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
3 assure the public that they were undertaking efforts to comply with their obligations under the
4 controlled substances laws, all with the goal of continuing to generate profits.

5 316. For example, a Cardinal Health executive claimed that it uses “advanced analytics”
6 to monitor its supply chain, and assured the public it was being “as effective and efficient as
7 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

8 317. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
9 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
10 curbing the opioid epidemic in our country.”⁸⁷

11 318. Defendants, through their trade associations, filed an amicus brief that represented
12 that Defendants took their duties seriously, complied with their statutory and regulatory
13 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

14 319. Defendants purposely concealed their wrongful conduct, including by assuring the
15 public and governmental authorities that they were complying with their obligations and were
16 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
17 behavior by providing the public with false information about opioids and have continued to use
18 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
19 is continuing to this day.

20 320. Defendants have also concealed and prevented discovery of information, including
21

22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
24 [https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
[7b6c1998b7a0_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html) (last accessed December 21, 2017)

25 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
Opioid Abuse, Wash. Post, (Dec. 22, 2016), available at
26 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html)
[industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html) (last accessed December 21,
27 2017).

28 ⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

1 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
2 and illegal activities.

3 321. Defendants also lobbied Congress and actively attempted to halt DEA investigations
4 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
5 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a
6 distributor's license was raised.

7 322. In addition, the Defendants fraudulently attempted to convince the public that they
8 were complying with their legal obligations and working to curb the opioid epidemic.

9 323. Because the Defendants concealed the facts surrounding the opioid epidemic, Costa
10 Mesa did not know if the existence or scope of the Defendants' misconduct, and could not have
11 acquired such knowledge earlier through the exercise of reasonable diligence.

12 324. Defendants intended that their false statements and omissions be relied upon,
13 including by Costa Mesa, its residents and physicians, and those coming to Costa Mesa for
14 "rehabilitation."

15 325. Defendants knew of their wrongful acts and had material information pertinent to
16 their discovery, but concealed that information from the public, including Costa Mesa, and its
17 residents. Only Defendants knew of their widespread misinformation campaign and of their
18 repeated, intentional failures to prevent opioid diversion.

19 326. Defendants cannot claim prejudice due to a late filing because this suit was filed
20 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
21 opioid crisis have only recently come to light.

22 327. Defendants had actual knowledge that their conduct was deceptive, and they
23 intended it to be deceptive.

24 328. Costa Mesa was unable to obtain vital information regarding these claims absent
25 any fault or lack of diligence on Costa Mesa's part.

26
27
28 ⁸⁹ See Higham and Bernstein, *supra* note 53.

1 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

2 **A. The Marketing Scheme**

3 329. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
4 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
5 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
6 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
7 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
8 long-term, chronic pain. Through their personal relationships, the members of this marketing
9 scheme had the opportunity to form and take actions in furtherance of their common purpose. The
10 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
11 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

12 330. The Manufacturer Defendants, through their marketing scheme, concealed the true
13 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
14 made misleading statements and misrepresentations about opioids that downplayed the risk of
15 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
16 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
17 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
18 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
19 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
20 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
21 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
22 formulations provide a solution to opioid abuse.

23 331. The marketing scheme devised, implemented and conducted by the Manufacturer
24 Defendants was designed to ensure that they unlawfully increased their sales and profits through
25 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
26 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
27 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
28 network as described above.

1 332. There was regular communication between the Manufacturer Defendants, Front
2 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
3 exchanged. Typically, the coordination, communication and payment occurred, and continues to
4 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
5 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
6 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
7 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
8 each agreed and took actions to hide the scheme and continue its existence.

9 333. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'
10 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
11 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
12 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
13 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
14 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
15 their members and constituents. By failing to disclose this information, Front Groups perpetuated
16 the marketing scheme, and reaped substantial benefits.

17 334. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
18 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
19 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
20 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
21 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
22 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
23 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
24 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
25 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
26 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
27 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
28 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

1 335. As public scrutiny and media coverage focused on how opioids ravaged
2 communities in California and throughout the United States, the Front Groups and KOLS did not
3 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
4 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
5 using opioids for chronic pain.

6 336. The Manufacturer Defendants, Front Groups and KOLS engaged in certain discrete
7 categories of activities in furtherance of the marketing scheme. As described herein, the
8 Manufacturer Defendants, Front Groups and KOLS' conduct in furtherance of the common purpose
9 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe
10 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
11 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
12 and (d) efforts to limit prescriber accountability.

13 337. In addition to disseminating misrepresentations about the risks and benefits of
14 opioids, Manufacturer Defendants, Front Groups and KOLS also furthered their common purpose
15 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLS
16 criticized or undermined the CDC Guidelines which represented "an important step – and perhaps
17 the first major step from the federal government - toward limiting opioid prescriptions for chronic
18 pain."

19 338. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
20 the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not
21 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
22 of the individuals who participated in the construction of these guidelines."

23 339. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
24 president, stating "that the CDC guideline makes disproportionately strong recommendations based
25 upon a narrowly selected portion of the available clinical evidence."

26 340. The Manufacturer Defendants alone could not have accomplished the purpose of the
27 marketing scheme without the assistance of the Front Groups and KOLS, who were perceived as
28 "neutral" and more "scientific" than the Manufacturer Defendants themselves. Without the work

1 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
2 scheme could not have achieved its common purpose.

3 341. The impact of the marketing scheme remains in place—i.e., the opioids continue to
4 be prescribed and used for chronic pain throughout Costa Mesa, and the epidemic continues to
5 injure Plaintiff, and consume the resources of Plaintiff’s emergency health and housing services
6 and law enforcement systems.

7 342. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
8 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
9 in the object of the scheme, and functioned within a structure designed to effectuate the scheme’s
10 purpose.

11 **B. The Distribution Scheme**

12 343. Faced with the reality that they will now be held accountable for the consequences
13 of the opioid epidemic they created, members of the industry resort to “a categorical denial of any
14 criminal behavior or intent.”⁹⁰ Defendants’ actions went far beyond what could be considered
15 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
16 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
17 competitive, with the common purpose and achievement of vastly increasing their respective profits
18 and revenues by exponentially expanding a market that the law intended to restrict.

19 344. Knowing that dangerous drugs have a limited place in our society, and that their
20 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
21 and addiction causes to individuals, society and governments, California enacted California
22 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
23 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
24 to detect and report such activity.

25 345. If morality and the law did not suffice, competition dictates that the Distributor
26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

1 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
2 if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior
3 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
4 dictates that it would do so.

5 346. The Distributor Defendants' scheme required the participation of all. If any one
6 member broke rank, its compliance activities would highlight deficiencies of the others, and the
7 artificially high quotas they maintained through their scheme would crumble. But, if all the
8 members of the enterprise conducted themselves in the same manner, it would be difficult for state
9 authorities or the DEA to go after any one of them. Accordingly, through the connections they
10 made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the
11 Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly,
12 in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting
13 Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, the
14 Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance
15 Guidelines, which recognize these Defendants' duties under the law, as illustrated by the
16 subsequent industry-wide enforcement actions and consent orders issued after that time, none of
17 them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult
18 to find the right balance between proactive anti-diversion efforts while not inadvertently limiting
19 access to appropriately prescribed and dispensed medications." Yet, the Distributor Defendants
20 apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure
21 the largest possible financial return.

22 347. As described above, at all relevant times, the Distributor Defendants conspired
23 together for the purpose of unlawfully increasing sales, revenues and profits. In support of this
24 common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard
25 their statutory duties to identify, investigate, halt and report suspicious orders of opioids and
26 diversion of their drugs into the illicit market so that those orders would not result in a decrease, or
27 prevent an increase in, the necessary quotas.

28 348. At all relevant times, as described above, the Distributor Defendants exerted control

over, conducted and/or participated in distribution scheme by fraudulently claiming that they were complying with their duties under California law to report suspicious orders and to maintain systems to detect and report such activity.

349. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators' ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the "Ensuring Patient Access and Effective Drug Enforcement Act."⁹¹

350. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

351. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

352. Defendants' causal role in the opioid epidemic was not broken by the involvement

⁹¹ HDMA is Now the Healthcare Distribution Alliance, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive
 2 messages tainted virtually every source doctors could rely on for information and prevented them
 3 from making informed treatment decisions. Defendants also were able to harness and hijack what
 4 doctors wanted to believe – namely, that opioids represented a means of relieving their patients'
 5 suffering and of practicing medicine more compassionately.

6 353. Each Defendant's conduct and role in creating or assisting in the creation of the
 7 public health crisis now plaguing California is directly relevant to the amount of the civil penalties
 8 to be awarded under California Business & Professions Code § 17536

9 354. As a members of the boards of various Purdue entities, the Sacklers oversaw all
 10 aspects of Purdue's marketing and promotion of opioid products. As board members who were
 11 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
 12 known, of Purdue's deceptive marketing tactics of opioid products.

13 355. The Sackler Defendants also were aware of specific examples of deceptive
 14 marketing through receipt of call note reviews in their capacities as board members. On information
 15 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
 16 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
 17 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

18 356. The Sackler Defendants were personally aware that: (1) OxyContin was being
 19 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
 20 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
 21 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

22 357. By 2006, prosecutors at the United States Department of Justice found damning
 23 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
 24 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
 25 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
 26 events and side effects than other pain medications.

27 358. As members of the family that owns Purdue, the Sackler Defendants personally
 28 benefitted from the success of OxyContin. At various points, as directors, they approved the

1 distribution of funds from Purdue to shareholders, including themselves and their extended family.

2 359. Since at least 1999, the Sackler Defendants were aware of potential liability for
3 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
4 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
5 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
6 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
7 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
8 the opioid related liabilities of the companies from which they were transferred.

9 360. Plaintiff is informed and believes that due to the billions of dollars in profits that
10 have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to
11 satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced
12 litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the
13 Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly
14 profited and received the benefits of that wrongdoing.

15 **VII. CAUSES OF ACTION**

16 **FIRST CAUSE OF ACTION**

17 **(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)**

18 361. Plaintiff realleges and incorporates herein by reference each and every allegation in
19 paragraphs 1 through 360 above as if set forth fully herein.

20 362. California Civil Code § 3479 provides that “anything which is injurious to health ...
21 or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to
22 interfere with the comfortable enjoyment of life or property ... is a nuisance.”

23 363. California Civil Code § 3480 defines a “public nuisance” as “one which affects at
24 the same time an entire community or neighborhood, or any considerable number of persons,
25 although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

26 364. California Civil Code § 3490 states that “no lapse of time can legalize a public
27 nuisance, amounting to an actual obstruction of public right.”

28 365. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought

1 by Costa Mesa to abate the public nuisance created by the Defendants.

2 366. Each Defendant, acting individually and in concert, has created or assisted in the
3 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment
4 of life and property of entire communities or neighborhoods or of any considerable number of
5 persons in Costa Mesa in violation of California Civil Code §§ 3479 and 3480.

6 367. The public nuisance is substantial and unreasonable. Defendants' actions caused and
7 continue to cause the public health epidemic described above in Costa Mesa, and that harm
8 outweighs any offsetting benefit.

9 368. Defendants knew and should have known that their promotion and distribution of
10 opioids was false and misleading and that their deceptive marketing scheme would create or assist
11 in the creation of the public nuisance—i.e., the opioid epidemic.

12 369. Defendants' actions were, at the very least, a substantial factor in opioids becoming
13 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
14 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
15 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
16 so widespread, and the opioid epidemic that now exists would have been averted or much less
17 severe.

18 370. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
19 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
20 can be abated.

21 371. Each Defendant is liable for public nuisance because its conduct at issue is
22 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
23 endangers the safety, health, morals, comfort, or repose of a considerable number of people in Costa
24 Mesa. Defendants' conduct is also indecent or offensive to the senses, and constitutes an obstruction
25 to the free use of property sufficient to constitute an interference with the people of Costa Mesa's
26 comfortable enjoyment of life or property.

27 372. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
28 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their

1 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
2 unreasonable interference with Costa Mesa and its residents' public rights, including, but not
3 limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to
4 be free from disturbance and reasonable apprehension of danger to person or property.

5 373. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
6 interfered with Costa Mesa and its residents' public rights by, *inter alia*, engaging in a promotion
7 and marketing scheme that pushed the use of opioids for indications not federally approved, and by
8 circulating false and misleading information concerning their risks, benefits, and superiority, and/or
9 downplaying or omitting the risk of addiction arising from their use. In so doing, Manufacturer
10 Defendants failed to comply with federal law.

11 374. Defendants have also unlawfully and intentionally distributed opioids or caused
12 opioids to be distributed within and without Costa Mesa absent effective controls against diversion.
13 Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures to maintain
14 effective controls against diversion include Defendants' failure to effectively monitor for
15 suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

16 375. Defendant's unreasonable interference with Costa Mesa residents' public rights
17 include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and increased
18 expenditures to combat and address these harms. These damages have been suffered and continue
19 to be suffered directly by Costa Mesa and its residents.

20 376. Defendants' actions have also created a palpable climate of fear, distress,
21 dysfunction and chaos among residents of Costa Mesa where opioid diversion, abuse, and addiction
22 are prevalent and where diverted opioids are used frequently. Specifically, Defendants conduct has
23 caused, among other things, (a) routine separation of children from their parents who have fallen
24 victim to easy access to opioids and/or related crime; (b) children to have easy access and to become
25 addicted to opioids; (c) residents to endure both the emotional and financial costs of caring for
26 loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of public spaces
27 and property; (e) property crimes throughout Costa Mesa; (f) employers to lose the value of
28 productive and healthy employees; (g) increased public health and safety costs; (h) a reduction in

1 potential property values within Costa Mesa and/or residents' use and enjoyment of their property;
 2 (i) harm to families and their residential neighborhoods and peaceful enjoyment of their properties
 3 due to the influx of people suffering from addiction caused by Defendants' misconduct; and (j) a
 4 decrease in tax revenues for Costa Mesa.

5 377. The impact of Defendants' conduct on Costa Mesa is of a continuing nature.
 6 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

7 378. Defendants knew or should have known that their actions would lead to the national
 8 opioid epidemic and to the resulting injuries to the public rights of Costa Mesa.

9 379. Costa Mesa has sustained a special and peculiar injury because its damages include,
 10 *inter alia*, health service expenditures, public safety expenditures, payment of opioid addiction
 11 treatment, decreased tax revenues, a reduction in potential property values and/or residents' use
 12 and enjoyment of their property, and other costs related to opioid addiction treatment and overdose
 13 prevention.

14 380. The externalized risks associated with Defendants' nuisance-creating conduct as
 15 described herein greatly exceed the internalized benefits.

16 381. Defendants' actions are a direct and proximate contributing cause of the opioid
 17 epidemic and the injuries to the public rights of Costa Mesa and its residents.

18 382. Defendants, individually and collectively, are at the very least, a substantial factor
 19 in causing the national opioid epidemic and of the injuries to Costa Mesa and its residents.

20 383. The injuries to the public rights of Costa Mesa and its residents are indivisible
 21 injuries.

22 384. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
 23 if unabated, will continue to cause an unreasonable interference with public rights of Costa Mesa
 24 and its residents.

25 385. Defendants' conduct is ongoing and persistent, and Costa Mesa seeks all damages
 26 flowing from Defendants' conduct. Costa Mesa seeks economic losses (direct, incidental, and/or
 27 consequential pecuniary losses) resulting from Defendants' illegal and wrongful conduct described
 28 above. Costa Mesa does not seek damages for the wrongful death, physical personal injury, or

1 emotional distress caused by Defendants' actions.

2 386. Pursuant to Code of Civil Procedure § 731, Costa Mesa requests an order providing
3 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
4 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

5 **SECOND CAUSE OF ACTION**
6 **(Fraud – Against All Defendants)**

7 387. Plaintiff realleges and incorporates herein by reference each and every allegation in
8 paragraphs 1 through 386 above as if set forth fully herein.

9 388. Plaintiff realleges and incorporates by reference the foregoing allegations as if set
10 forth herein

11 389. The Defendants made fraudulent misrepresentations and omissions of material fact.
12 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
13 were intended to induce reliance.

14 390. Those misrepresentations and omissions were known to be untrue by the
15 Defendants, or were recklessly made.

16 391. As alleged herein, the Manufacturer Defendants engaged in false representations
17 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
18 dangers of abuse, and the risks of addiction.

19 392. As alleged herein, Defendants made false statements and/or omissions regarding
20 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
21 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
22 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
23 opioids, within Costa Mesa.

24 393. Defendants made those misrepresentations and omissions in an intentional effort to
25 deceive Costa Mesa and its residents, despite the Defendants' knowledge of the dangers of such
26 use of prescription opioids.

27 394. In addition and independently, Defendants had a duty not to deceive Plaintiff
28 because Defendants had in their possession unique material knowledge that was unknown, and not

1 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

2 395. The Defendants continued making those misrepresentations, and failed to correct
3 those material omissions, despite repeated regulatory settlements and publications demonstrating
4 the false and misleading nature of the Defendants' omissions and/or claims.

5 396. While Defendants had a duty to disclose the above-referenced material facts, they
6 nevertheless concealed them. These false representations and concealed facts were material to the
7 conduct and actions at issue. Defendants made these false representations and concealed facts with
8 knowledge of the falsity of their representations and did so with the intent of misleading Costa
9 Mesa, its residents, the public, and persons on whom these entities relied.

10 397. Defendants intended and had reason to expect under the operative circumstances
11 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
12 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
13 and that these entities would act or fail to act in reasonable reliance thereon.

14 398. Costa Mesa, its residents, and others, did in fact rightfully, reasonably, and
15 justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

16 399. For instance, doctors, including those serving Costa Mesa and its residents, relied
17 on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain relief.
18 Patients, including residents of Costa Mesa, relied on the Defendants' misrepresentations and
19 omissions in taking prescription opioids for chronic pain relief.

20 400. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
21 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
22 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
23 effective response to the opioid crisis.

24 401. Defendants' misconduct alleged in this case is ongoing and persistent.

25 402. Costa Mesa has experienced an unprecedented opioid addiction and overdose
26 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
27 services, and lost productivity to Costa Mesa's workforce.

28 403. The injuries alleged by Plaintiff herein were sustained as a direct and proximate

1 result of Defendants' fraudulent conduct.

2 404. As a direct and foreseeable consequence of Defendants' fraud, Costa Mesa has
3 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
4 opioid addiction treatment and its secondary consequences in excess of those Costa Mesa would
5 have otherwise incurred.

6 405. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
7 fraudulent, entitling Costa Mesa to punitive damages.

8 **THIRD CAUSE OF ACTION**
9 **(Negligence – Against All Defendants)**

10 406. Plaintiff realleges and incorporates herein by reference each and every allegation in
11 paragraphs 1 through 405 above as if set forth fully herein.

12 407. To establish actionable negligence in California, Plaintiff must show a duty, a breach
13 of that duty, and injury resulting proximately therefrom.

14 408. Defendants have a duty to exercise reasonable care under the circumstances, in light
15 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
16 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
17 and still have, a duty to exercise reasonable care to prevent the threatened harm.

18 409. In addition, Defendants had a duty not to breach the standard of care established
19 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
20 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
21 to abuse, and to develop and maintain systems to detect and report such activity.

22 410. Defendants voluntarily undertook a legal duty to prevent the diversion of
23 prescription opioids by engaging in the distribution of prescription opioids and by making public
24 promises to prevent the diversion of prescription opioids.

25 411. Defendants knew of the serious problem posed by prescription opioid diversion and
26 were under a legal obligation to take reasonable steps to prevent diversion.

27 412. Defendants knew of the highly addictive nature of prescription opioids and of the
28 high likelihood of foreseeable harm to patients and communities, including Costa Mesa, from

1 prescription opioid diversion.

2 413. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
3 in accordance with applicable standards of conduct in advertising, marketing, selling, and
4 distributing opioid products in a safe manner to minimize the risk of addiction in patients and
5 resultant harm to those patients, their families and their communities, and to taxpayers and
6 municipal government such as Costa Mesa which must incur enormous expenditures for
7 prevention, treatment, emergency response and law enforcement costs and other foreseeable costs
8 related to the need to address the consequences of a large number of residents that become addicted
9 to opioids as a result of Defendants' conduct.

10 414. As described throughout the Complaint, Defendants breached their duties to
11 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
12 monitor for, failing to report, and filling highly suspicious orders time and again.

13 415. As described throughout the Complaint, in language expressly incorporated herein,
14 Defendants misrepresented their compliance with their duties under the law and concealed their
15 noncompliance and shipments of suspicious orders of opioids to Costa Mesa and destinations from
16 which they knew opioids were likely to be diverted into Costa Mesa, in addition to other
17 misrepresentations alleged and incorporated herein.

18 416. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
19 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
20 purported benefits of long-term use of opioids for the treatment of chronic pain.

21 417. Manufacturer Defendants knew or should have known, that their affirmative
22 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
23 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
24 representatives, and internal documents, should have put them on notice that such harm was not
25 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
26 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
27 and the public.

28 418. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct

1 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

2 419. Defendants' misconduct alleged in this case is ongoing and persistent.

3 420. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
4 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
5 great probability of causing substantial harm.

6 421. As is described throughout this Complaint, Defendants acted without even slight
7 diligence or scant care, and with indifference, and were negligent in a very high degree,
8 disregarding the rights and safety of other persons, and said actions have a great probability of
9 causing substantial harm.

10 422. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*
11 (1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill
12 in the in advertising, marketing, selling and distributing opioid products in a safe manner to
13 minimize the risk of addiction in patients and resultant harm to those patients, their families and
14 their communities, and to taxpayers and municipal government such as Costa Mesa, following:

- 15 a. Foreseeability of harm to Costa Mesa: Defendants were aware or reasonably
16 should have been aware of the risk of addiction of a large number of patients in
17 places such as Costa Mesa, and need for their care and treatment and in handling
18 other consequences of their addiction and that such costs would be borne by
19 local governments such as Costa Mesa;
- 20 b. Degree of certainty Costa Mesa suffered harm: Costa Mesa has suffered
21 enormous harm and costs in addressing treatment of addicted patients, including
22 but not limited to expenditures for prevention, treatment, emergency response
23 and law enforcement costs and other foreseeable costs related to the need to
24 address the consequences of a large number of residents that become addicted
25 to opioids as a result of Defendants' conduct;

- c. Closeness of connection between Costa Mesa's harm: The explosion of opioid addiction and the presence of opioid addicted patients in Costa Mesa as a result of Defendants' conduct has resulted in expenditures directly for increased health insurance costs, prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences;
- d. Moral blame attached to Defendants' conduct: Defendants' knew or should have known that their wrongful conduct, actions and omissions would result in an explosion of patients who would become addicted to opioids, and that a vast opioid epidemic would result from the prescription of opioids to tens of millions of patients nationwide, including within Costa Mesa, and that the costs would be borne by the state, county and municipal local governments, while Defendants profited tens of billions of dollars collectively from the widespread use of prescription opioid products;
- e. Policy of preventing future harm: As a direct and foreseeable result of Defendants' wrongful conduct, the opioid epidemic and crisis has and continues to occur on a vast scale both nationally and locally in places such as Costa Mesa resulting in tremendous harm and cost to the patients, their families and the communities in dealing with this epidemic and crisis, and there is a need to ensure that the costs of such wrongful conduct is borne by Defendants so that parties contemplating such or similar conduct in the future know they will be held responsible for such harm;
- f. Extent of burden to Defendants: There is no burden to Defendants in that state and other law precludes them from engaging in the conduct alleged herein, and

1 there is no burden from precluding Defendants from profiting from their
2 wrongful conduct and operating within the confines of the law in advertising,
3 marketing, selling and distributing opioid products in a safe manner to minimize
4 the risk of addiction in patients and resultant harm to those patients, their
5 families and their communities, and to taxpayers and municipal government
6 such as Plaintiff Costa Mesa; and

7
8 g. Consequences to the community of imposing a duty to exercise care with
9 resulting liability for breach: Imposing a duty to not engage in Defendants'
10 wrongful conduct of advertising, marketing, selling and distributing opioid
11 products in an unsafe manner would minimize the risk of addiction in patients,
12 and liability for a breach of this duty would benefit communities such as Costa
13 Mesa in that they would not have to incur the foreseeable costs of the opioid
14 epidemic gripping the country and the nation.

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16 423. Plaintiff is not asserting a cause of action under the CSA or other federal controlled
17 substances laws cited above.

18 424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
19 and will continue to suffer economic damages including, but not limited to, significant expenses
20 for security services, emergency, health, housing, prosecution, corrections, and rehabilitation
21 services, as well as the cost of opioid addiction treatment and insurance paid by Costa Mesa.

22 425. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
23 and will continue to suffer stigma damage, non-physical property damage, and damage to its
24 proprietary interests.

25 426. Defendants' breaches of their duty of care foreseeably and proximately caused
26 damage to Costa Mesa and its residents.

27 427. Manufacturer Defendants are guilty of negligence per se in that the Defendants
28

1 violated applicable California laws, statutes, and regulations, in the manner in which they
2 advertised, marketed, sold and distributed opioid products.

3 428. Distributor Defendants are guilty of negligence per se in that the Defendants violated
4 California laws, statutes, and regulations designed to protect Plaintiff from the harms it has suffered
5 including but not limited to the following:

- 6 a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug,
7 and Cosmetic Laws, California Health & Safety Code § 110390;
- 8 b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that
9 had been falsely advertised in violation of the Sherman Food, Drug, and
10 Cosmetic Laws, California Health & Safety Code § 110395;
- 11 c. Defendants received in commerce opioids that were falsely advertised or
12 delivered or proffered for delivery opioids that were falsely advertised in
13 violation of the Sherman Food, Drug, and Cosmetic Laws, California Health &
14 Safety Code § 110400;
- 15 d. Defendants failed to report all sales of dangerous drugs subject to abuse in
16 excess of the amounts set by the California State Board of Pharmacy in violation
17 of 16 C.C.R. §1782;
- 18 e. Defendants failed to track and report all purchases that exceeded prior purchases
19 by long-term care facilities or similar customers by a factor of 20 percent in
20 violation of California Business & Professions Code § 4164; and
21 f. Defendants failed to report all suspicious orders placed by California pharmacies
22 or wholesalers after January 1, 2018 as required by California Business &
23 Professions Code § 4169.1.

24 429. As a direct and proximate consequence of Defendants' negligent acts, omissions,
25 misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic,
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1 including in Costa Mesa. Costa Mesa, as a further direct and proximate consequence and result
2 thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs
3 for treatment of opioid addicted patients, emergency response costs, housing, law and regulatory
4 enforcement costs, and measures for prevention of further opioid abuse and addiction.

5 430. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
6 fraudulent, entitling Costa Mesa to punitive damages.

7 **FOURTH CAUSE OF ACTION**
8 **(Unjust Enrichment – Against All Defendants)**

9 431. Plaintiff realleges and incorporates herein by reference each and every allegation in
10 paragraphs 1 through 430 above as if set forth fully herein.

11 432. As an expected and intended result of their conscious wrongdoing as set forth in this
12 Complaint, Defendants have profited and benefited from the increase in the distribution and
13 purchase of opioids within Costa Mesa, including from opioids foreseeably and deliberately
14 diverted within and into Costa Mesa.

15 433. Plaintiff has expended substantial amounts of money in an effort to remedy or
16 mitigate the societal harms caused by Defendants' conduct.

17 434. These expenditures include, but are not limited to, emergency medical services and
18 treatment services to people who use opioids.

19 435. These expenditures have helped sustain Defendants' businesses.

20 436. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
21 externalities: the cost of the harms caused by Defendants' improper distribution practices.

22 437. Defendants were aware of these obvious benefits, and their retention of the benefit
23 is unjust.

24 438. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
25 benefited from those payments because they allowed them to continue providing customers with a
26 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
27 Defendants obtained enrichment they would not otherwise have obtained. Because of their
28 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment

1 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
2 lacks a remedy provided by law.

3 439. Defendants' misconduct alleged in this case is ongoing and persistent.

4 440. Defendants have unjustly retained benefits to the detriment of Costa Mesa, and
5 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
6 good conscience.

7 441. Costa Mesa is entitled to restitution and disgorgement from Defendants in an amount
8 to be determined at trial.

9 **FIFTH CAUSE OF ACTION**
10 **(Civil Conspiracy – Against All Defendants)**

11 442. Plaintiff realleges and incorporates herein by reference each and every allegation in
12 paragraphs 1 through 441 above as if set forth fully herein.

13 443. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids
14 and/or distribution of opioids into California and Costa Mesa.

15 444. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in
16 conjunction with their unlawful marketing of opioids and/or distribution of opioids into California
17 and Costa Mesa.

18 445. Defendants unlawfully failed to act to prevent diversion and failed to monitor for,
19 report, and prevent suspicious orders of opioids.

20 446. The Manufacturing Defendants further unlawfully coordinated in furtherance of the
21 conspiracy by increasing the volume of opioid sales in the United States through creating a market
22 for non-medical use of opioids of epidemic proportions.

23 447. Many of the Manufacturing Defendants are members, participants, and/or sponsors
24 of the Healthcare Distribution Alliance ("HDA"), and have been since at least 2006, and utilized
25 the HDA to give further assistance to the conspiracy.

26 448. The Manufacturing Defendants hid from the general public and suppressed and/or
27 ignored warnings from third parties, whistleblowers, and governmental entities about the reality of
28 the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead

1 to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

2 449. The Manufacturing Defendants, with knowledge and intent, agreed to the overall
3 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
4 to commit acts of fraud.

5 450. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had
6 to agree to implement similar tactics.

7 451. By intentionally refusing to report and halt suspicious orders of their prescription
8 opioids, Defendants engaged in a fraudulent scheme.

9 452. Nevertheless, in order to increase sales of their opioid products in furtherance of the
10 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
11 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
12 and were actually being diverted into the market of non-medical use.

13 453. Defendants further unlawfully marketed opioids in California and Costa Mesa in
14 furtherance of that conspiracy to increase profits and sales through the knowing and intentional
15 dissemination of false and misleading information about the safety and efficacy of long-term opioid
16 use through, among other things: (a) the use of "Front Groups" that appeared to be independent of
17 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
18 continuing medical education ("CME") programs controlled and/or funded by the Defendants; (d)
19 hiring and deploying so-called "key opinion leaders" or "KOLs" who were paid by the Defendants
20 to promote their message; and (e) the "detailing" activities of the Defendants' sales forces, which
21 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
22 physicians lacking the expertise of pain care specialists.

23 454. Each of the Front Groups helped disguise the role of Defendants by purporting to be
24 unbiased, independent patient-advocacy and professional organizations in order to disseminate
25 patient education materials, a body of biased and unsupported scientific "literature," and "treatment
26 guidelines" that promoted the Defendants' false messages.

27 455. Each of the KOLs were physicians chosen and paid by each of the Defendants to
28 influence prescribers' habits by promoting the Defendants' false message through, among other

1 things, writing favorable journal articles and delivering supportive CMEs as if they were
2 independent medical professionals, thereby further obscuring the Defendants' role in the
3 conspiracy.

4 456. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
5 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
6 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
7 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
8 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs
9 were industry-friendly and would work together with the Defendants to advance the conspiracy.

10 457. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this
11 Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes.
12 Such allegations are specifically incorporated herein.

13 458. Defendants acted with a common understanding or design to commit unlawful acts,
14 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
15 proximately caused the injuries alleged herein.

16 459. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
17 reasonable or lawful excuse.

18 460. Defendants conduct in furtherance of the conspiracy described herein was not mere
19 parallel conduct because each Defendant acted directly against their commercial interests in not
20 reporting the unlawful distribution practices of their competitors to the authorities, which they had
21 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
22 actual or tacit agreement between the Defendants that they would not report each other to the
23 authorities so they could all continue engaging in their unlawful conduct.

24 461. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
25 thereof, caused the direct and foreseeable losses alleged herein.

26 462. Defendants' misconduct alleged in this case is ongoing and persistent.

27 463. As a result of Defendants' conspiracy, Costa Mesa is entitled to compensatory
28 damages in an amount to be proved at trial.

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(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)

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1 preventing suspicious orders.

2 474. As alleged above, Defendants' statements about the risks associated with opioid use
3 were not supported by or were contrary to the scientific evidence.

4 475. As alleged above, each Defendant's conduct, separately and collectively, was likely
5 to deceive California payors who purchased or covered the purchase of opioids.

6 476. Costa Mesa seeks restitution and injunctive relief under California Business &
7 Professions Code § 17535.

8 477. Costa Mesa also seeks an order assessing a civil penalty of two thousand five
9 hundred dollars (\$2,500) against Defendants for each violation of California's False Advertising
10 Law pursuant to California Business & Professions Code § 17536.

11 **SEVENTH CAUSE OF ACTION**
12 **(Negligent Failure to Warn— Against Manufacturer Defendants)**

13 478. Plaintiff realleges and incorporates herein by reference each and every allegation in
14 paragraphs 1 through 477 above as if set forth fully herein.

15 479. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
16 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
17 adequately warning the medical profession about the risk of addiction from the use of opioid
18 products, and not to over-promote and over-market opioid products in a manner so as to nullify,
19 cancel out, and render meaningless any written warnings given about the risk of addiction from the
20 use of opioid products.

21 480. Defendants breached their duty to exercise reasonable and ordinary care by failing
22 to adequately warn the medical profession about the risk of addiction from the use of opioid
23 products, including by over-promoting and over-marketing opioid products in a manner so as to
24 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
25 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
26 products in situations and for patients who should not have been using those drugs or should have
27 used them only as a last resort before other means were used or other less addictive and dangerous
28 drugs were prescribed.

1 481. As a direct and proximate consequence of Defendants' negligent failure to warn,
2 and over-promoting and over-marketing the use of prescription opioid products, there is now a
3 national opioid addiction epidemic, including in Costa Mesa. The People, as a further direct and
4 proximate consequence and result thereof, sustained injuries and damages including but not limited
5 to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs,
6 law and regulatory enforcement costs, housing, opioid disposal programs, and measures for
7 prevention of further opioid abuse and addiction.

8 482. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and
9 fraudulent, entitling Costa Mesa to punitive damages.

10 **EIGHTH CAUSE OF ACTION**
11 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler**
12 **Defendants)**

13 483. Plaintiff realleges and incorporates herein by reference each and every allegation in
14 paragraphs 1 through 481 above as if set forth fully herein.

15 484. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
16 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
17 possess a right to payment from Purdue.

18 485. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
19 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
20 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
21 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

22 486. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
23 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
24 including Plaintiff.

25 487. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
26 them pursuant to California Civil Code § 3439.04(a)(1).

27 **NINTH CAUSE OF ACTION**
28 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

 488. Plaintiff realleges and incorporates herein by reference each and every allegation in

1 paragraphs 1 through 4888 above as if set forth fully herein.

2 489. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
3 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
4 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
5 of its judgment against Purdue entered in this action.

6 490. After the Sackler Defendants became aware in or about 1999 that Purdue faced
7 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
8 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping
9 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
10 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
11 Defendants and their extended family.

12 491. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
13 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
14 to commit acts of fraud.

15 492. Purdue and the Sackler Defendants acted with a common understanding or design
16 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
17 excuse, which directly and proximately caused the injuries alleged herein.

18 493. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
19 unlawfully, and without a reasonable or lawful excuse.

20 494. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
21 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
22 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
23 judgment entered in this action.

24 495. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
25 compensatory damages in an amount to be proved at trial.

26 496. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
27 malicious, oppressive, and fraudulent, entitling plaintiff to punitive damages.
28

PRAYER FOR RELIEF

WHEREFORE, Costa Mesa and the People respectfully request judgment in their favor granting the following relief:

- a) Entering Judgment in favor of Costa Mesa and the People in a final order against each of the Defendants;
- b) An award of actual and consequential damages in an amount to be determined at trial;
- c) An order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment

of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;

- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff's judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;
- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;
- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and
- v) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Dated: March 27, 2019

ROBINS KAPLAN LLP

By:



Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

EXHIBIT J

**SUMMONS
(CITACION JUDICIAL)**

SUM-100

NOTICE TO DEFENDANT: PURDUE PHARMA L.P.;
(AVISO AL DEMANDADO): (additional Parties Attachment form is attached)

FOR COURT USE ONLY
 (SOLO PARA USO DE LA CORTE)
**ENDORSED
 FILED
 ALAMEDA COUNTY**

MAR 28 2019

CLERK OF THE SUPERIOR COURT

By

Jayana Turner
 Deputy

**YOU ARE BEING SUED BY PLAINTIFF: COUNTY OF ALAMEDA; and
 (LO ESTÁ DEMANDANDO EL DEMANDANTE): THE PEOPLE OF THE
 STATE OF CALIFORNIA, by and through Alameda County
 Counsel Donna Ziegler**

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (www.lawhelpcalifornia.org), the California Courts Online Self-Help Center (www.courtinfo.ca.gov/selfhelp), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of \$10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case. **AVISO!** Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. **AVISO:** Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de \$10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:

(El nombre y dirección de la corte es):

Alameda County Superior Court
 Oakland - Rene C. Davidson Courthouse
 1225 Fallon Street
 Oakland, CA 94612

CASE NUMBER:

(Número del Caso):

2019012601

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:

(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):

Roman Silberfeld, Bar No. 62783 310-552-0130 310-229-5800
 Lucas A. Messenger, Bar No. 217645
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 Los Angeles, CA 90067

DATE:

(Fecha)

MAR 28 2019

Chad Finke

Clerk, by

(Secretario)

Deputy

(Adjunto)

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)

(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, (POS-010)).

NOTICE TO THE PERSON SERVED: You are served

1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (specify):
3. ☐ on behalf of (specify):

under: ☐ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
☐ other (specify):

4. ☐ by personal delivery on (date):

[SEAL]

Page 1 of 1

SUM-200(A)

SHORT TITLE: County of Alameda, et al. v. Purdue Pharma
L.P., et al.

CASE NUMBER:

INSTRUCTIONS FOR USE

- ➔ This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- ➔ If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties (Check only one box. Use a separate page for each type of party.):

☐ Plaintiff ☒ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

PURDUE PHARMA INC.;
 THE PURDUE FREDERICK COMPANY;
 RICHARD S. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 JONATHAN D. SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY;
 MORTIMER D.A. SACKLER, an individual;
 KATHE A. SACKLER, an individual;
 IRENE SACKLER LEFCOURT, an individual;
 BEVERLY SACKLER, an individual and as trustee for TRUST FOR THE BENEFIT OF
 MEMBERS OF THE RAYMOND SACKLER FAMILY; THERESA SACKLER, an individual;
 DAVID A. SACKLER, an individual;
 CEPHALON, INC.;
 TEVA PHARMACEUTICAL INDUSTRIES, LTD.;
 TEVA PHARMACEUTICALS USA, INC.;
 JANSSEN PHARMACEUTICALS, INC.;
 JOHNSON & JOHNSON;
 ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.;
 JANSSEN PHARMACEUTICA, INC.;
 ENDO HEALTH SOLUTIONS INC.;
 ENDO PHARMACEUTICALS INC.;
 ACTAVIS PLC; WATSON PHARMACEUTICALS, INC.;
 WATSON LABORATORIES, INC.;
 ACTAVIS PHARMA, INC.;
 ACTAVIS LLC;
 ALLERGAN PLC;
 ALLERGAN, INC.;
 ALLERGAN USA, INC.;
 INSYS THERAPEUTICS, INC.;
 MALLINCKRODT, PLC;
 MALLINCKRODT, LLC;
 CARDINAL HEALTH, INC.;
 AMERISOURCEBERGEN CORPORATION;
 MCKESSON CORPORATION; and
 DOES 1-100, inclusive,

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The People of the State of California

(NO FEE – Cal. Gov. Code § 6103)

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

COUNTY OF ALAMEDA; and THE
PEOPLE OF THE STATE OF
CALIFORNIA, by and through Alameda
County Counsel Donna Ziegler,

Plaintiffs,

v.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RICHARD S.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; JONATHAN D.
SACKLER, an individual and as trustee for
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; MORTIMER D.A.
SACKLER, an individual; KATHE A.

ENDORSED
FILED
ALAMEDA COUNTY

MAR 28 2019

CLERK OF THE SUPERIOR COURT

By *[Signature]*

Case No. *19012661*

PLAINTIFFS' COMPLAINT FOR:

1. PUBLIC NUISANCE;
2. FRAUD;
3. NEGLIGENCE;
4. UNJUST ENRICHMENT;
5. CIVIL CONSPIRACY;
6. FALSE ADVERTISING;
7. NEGLIGENT FAILURE TO WARN;
8. FRAUDULENT TRANSFER; and

1 SACKLER, an individual; IRENE
 2 SACKLER LEFCOURT, an individual;
 3 BEVERLY SACKLER, an individual and
 4 as trustee for TRUST FOR THE BENEFIT
 5 OF MEMBERS OF THE RAYMOND
 6 SACKLER FAMILY; THERESA
 7 SACKLER, an individual; DAVID A.
 8 SACKLER, an individual; CEPHALON,
 9 INC.; TEVA PHARMACEUTICAL
 10 INDUSTRIES, LTD.; TEVA
 11 PHARMACEUTICALS USA, INC.;
 12 JANSSEN PHARMACEUTICALS, INC.;
 13 JOHNSON & JOHNSON; ORTHO-
 14 MCNEIL-JANSSEN
 15 PHARMACEUTICALS, INC.; JANSSEN
 16 PHARMACEUTICA, INC.; ENDO
 17 HEALTH SOLUTIONS INC.; ENDO
 18 PHARMACEUTICALS INC.; ACTAVIS
 19 PLC; WATSON PHARMACEUTICALS,
 20 INC.; WATSON LABORATORIES, INC.;
 21 ACTAVIS PHARMA, INC.; ACTAVIS
 22 LLC; ALLERGAN PLC; ALLERGAN,
 23 INC.; ALLERGAN USA, INC.; INSYS
 24 THERAPEUTICS, INC.;
 25 MALLINCKRODT, PLC;
 26 MALLINCKRODT, LLC; CARDINAL
 27 HEALTH, INC.;
 28 AMERISOURCEBERGEN
 CORPORATION; MCKESSON
 CORPORATION; and
 DOES 1-100, inclusive,

Defendants.

9. CIVIL CONSPIRACY

Table of Contents

I.	INTRODUCTION	1
II.	THE PARTIES.....	3
A.	The Plaintiffs.....	3
B.	The Manufacturer Defendants.....	3
C.	The Distributor Defendants.....	10
D.	The Doe Defendants.....	11
III.	JURISDICTION AND VENUE	12
IV.	GENERAL FACTUAL ALLEGATIONS.....	12
A.	An Overview of the Opioid Epidemic	12
B.	The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids.....	16
1.	The Manufacturer Defendants Engaged in False and Misleading Direct Marketing of Opioids	19
2.	The Manufacturer Defendants Used Detailing and Speaker Programs to Spread False and Misleading Information About Opioids	19
3.	The Manufacturer Defendants Deceptively Marketed Opioids through Seemingly Independent Third Parties that Disseminated Unbranded Advertising Created by the Manufacturer Defendants.....	22
C.	The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False.....	31
D.	The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy	44
E.	All Defendants Created an Illicit Market for Opioids.....	54
1.	The Distributor Defendants Negligently Failed to Control the Flow of Opioids to Alameda County Through Illicit Channels	57
2.	The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Alameda County Through Illicit Channels.....	64
F.	The Defendants Knowingly Profit from an Interstate Opioid Crisis	65
G.	Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages.....	70
H.	The Impact of Opioid Abuse on Alameda County.....	72
I.	The Statutes of Limitations Are Tolloed and Defendants Are Estopped from Asserting Statutes of Limitations As Defenses.....	78
V.	FACTS PERTAINING TO DEFENDANTS' CONSPIRACY	80
A.	The Marketing Scheme	80
B.	The Distribution Scheme.....	84
VI.	MISCELLANEOUS FACTUAL ALLEGATIONS	86
VII.	CAUSES OF ACTION	88

I. INTRODUCTION

1. An epidemic of prescription opioid abuse is devastating the United States. Plaintiff County of Alameda (hereinafter, “Alameda County”) has been particularly hard hit, causing Alameda County to suffer substantial loss of resources, economic damages, and damages to the health and welfare of its citizens.

2. Alameda, California, by and through its attorneys hereto and its Office of County Counsel, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California (the “People,” and together with Alameda County, “Plaintiff”) to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

3. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid addiction and overdose deaths.¹ The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”²

4. This epidemic has been building for years. The conditions for its creation and acceleration were intentionally brought about by Defendants, who made billions of dollars off the epidemic.

5. The effects of the opioid epidemic and resulting health care crisis have been exacerbated by Defendants’ efforts to conceal or minimize the risks of opioid abuse, while at the same time circumventing or ignoring any safeguards against opioid abuse.

6. Alameda County has seen increased costs of, among other things, (a) medical and therapeutic care, and other treatment costs for patients suffering from opioid addiction, overdose, or death; (b) counseling, treatment and rehabilitation services; (c) treatment of infants born with opioid-related medical conditions; (d) welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation, including costs of related legal proceedings; (e)

¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

1 public safety connected to the opioid epidemic within Alameda County, including police,
2 emergency response services, and detention centers; (f) increased burden on Alameda County's
3 judicial system; (g) re-education of doctors and patients about the appropriate use of opioids; and
4 (h) extensive clean-up of public parks, spaces, and facilities. At the same time, Alameda County
5 has seen a reduction to tax revenues caused by the epidemic created by the Defendants. Almost
6 every citizen of Alameda County has been affected. The resulting damage to Alameda County was
7 directly and foreseeably caused by Defendants' actions.

8 7. These increased costs could have been—and should have been—prevented by the
9 opioid industry. Defendants controlled the manufacture, marketing, and distribution of prescription
10 opioids. As such Defendants, and not Plaintiff, were in the best position to protect Plaintiff from
11 the risk of harm stemming from misuse of these products. Defendants owed Plaintiff a duty of care
12 to act reasonably in light of that potential harm. The opioid industry also is required by statute and
13 regulation to secure and monitor opioids at every step of the stream of commerce, thereby
14 protecting opioids from theft, misuse, and diversion.

15 8. Instead of acting with reasonable care and in compliance with their legal duties,
16 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
17 process.

18 9. At the same time, Defendants flooded the market with false statements designed to
19 persuade both doctors and patients that prescription opioids posed a low risk of addiction. Those
20 claims were false.³

21 10. Defendants' actions have not only caused significant costs, but also have created a
22 palpable climate of fear, distress, dysfunction, and chaos among Alameda County residents where
23 opioid diversion, abuse, and addiction are prevalent and where diverted opioids tend to be used
24 frequently.

25 11. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful
26 and/or unlawful conduct.

27
28 ³ See Vivek H. Murthy, *Letter from the Surgeon General* (August 2016), available at
<http://turnthetidex.org/> (last accessed December 18, 2017).

II. THE PARTIES**A. The Plaintiffs**

12. The County of Alameda, California and the People of the State of California, by and through their attorneys hereto and its Office of County Counsel, hereby brings this action on its own behalf for injuries suffered and on behalf of the People of the State of California to protect the public from false and misleading advertising, fraudulent acts, negligent acts, and a public nuisance.

13. Alameda County has standing to recover damage incurred because of Defendants' actions and omissions. Alameda County has standing to bring actions including, *inter alia*, public nuisance claims asserted under state law.

B. The Manufacturer Defendants

14. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. Also at all relevant times, the Manufacturer Defendants have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

15. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

16. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁴ and Targiniq ER in the United States, including California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁴ Long-acting or extended release ("ER" or "ER/LA") opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release ("IR") opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 17. In May 2007, Purdue entered into a stipulated final judgment with the State of
4 California, acting by and through the California Attorney General, based principally on Purdue's
5 direct promotion of OxyContin through May 8, 2007, which is the effective date of the stipulated
6 final judgment (the "Purdue Final Judgment"). Through this Complaint, the People do not seek to
7 enforce any provision of the Purdue Final Judgment. The People also are not seeking any relief
8 against Purdue under any state consumer protection law (as that term is defined by section (I)(1)(M)
9 and footnote 1 of the Purdue Final Judgment) or based on any conduct by Purdue relating to its
10 promotional and marketing practices regarding OxyContin at any time up to and including May 8,
11 2007. The People, however, do assert claims arising under California law independent of the Purdue
12 Final Judgment, and seek civil penalties and injunctive relief as afforded by those laws.

13 18. Richard S. Sackler is a natural person residing in Travis County, Texas. He is the
14 son of Purdue founder Raymond Sackler, and beginning in the 1990's, served as a member of the
15 board of directors of Purdue and Purdue-related entities. Richard S. Sackler is also a trustee of The
16 Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust"),
17 which is the 50% direct or indirect beneficial owner of Purdue and Purdue related entities and the
18 recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

19 19. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut.
20 He is the son of Purdue founder Raymond Sackler, and has been a member of the board of directors
21 of Purdue and Purdue-related entities since the 1990's. Jonathan D. Sackler is also a trustee of the
22 Raymond Sackler Trust.

23 20. Mortimer D.A. Sackler is a natural person residing in New York County, New York.
24 He is the son of Purdue founder Mortimer Sackler. Mortimer D.A. Sackler and has been a member
25 of the board of directors of Purdue and Purdue-related entities since the 1990's.

26 21. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She
27 is the daughter of Purdue founder Mortimer Sackler, and has served as a member of the board of
28 directors of Purdue and Purdue-related entities since the 1990's.

22. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Purdue founder Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

23. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Purdue founder Raymond Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's. Beverly Sackler is also a trustee of the Raymond Sackler Trust.

24. Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Purdue founder Mortimer Sackler, and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990's.

25. David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler), and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012. Together, Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler and the Trust for the Benefit of the Members of the Raymond Sackler Family will hereinafter be collectively referred to as the "Sacklers" or the "Sackler Defendants." The Sackler Defendants are included in the defined term "Purdue," which is defined in paragraph 15 above. Thus, any causes of action asserted against Purdue as a Manufacturer Defendant in this Complaint are asserted against the Sackler Defendants as well.

26. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In October 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania.

27. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the United States, including California. Significantly, the FDA only approved Actiq and Fentora for the management of breakthrough cancer pain in patients who are tolerant to around-

1 the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon, Inc. pleaded
2 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
3 promotion of Actiq and two other drugs and agreed to pay \$425 million.

4 28. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
5 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
6 Cephalon, Inc. in the United States through Teva USA and has done so since its October 2011
7 acquisition of Cephalon, Inc. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products
8 to the public. Teva USA sells all former Cephalon-branded products through its “specialty
9 medicines” division. The FDA approved prescribing information and medication guide, which is
10 distributed with Cephalon opioids marketed and sold in California, discloses that the guide was
11 submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva
12 Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on
13 prescription savings cards distributed in California, indicating Teva Ltd. would be responsible for
14 covering certain co-pay costs.

15 29. All of Cephalon, Inc.’s promotional websites, including those for Actiq and Fentora,
16 prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon, Inc.’s and Teva’s
17 USA’s sales as its own, and its year-end report for 2012—the year immediately following the
18 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion
19 of a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
20 operates in California and the rest of the United States through its subsidiaries Cephalon, Inc. and
21 Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its
22 global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva
23 Ltd. would conduct those companies’ business in the United States itself. Upon information and
24 belief, Teva Ltd. directs the business practices of Cephalon, Inc. and Teva USA, and their profits
25 inure to the benefit of Teva Ltd. as controlling shareholder. (together, Teva Ltd., Teva USA, and
26 Cephalon, Inc. are referred to as “Cephalon”). Teva Branded Pharmaceutical Products R&D, Teva
27 Neuroscience, Teva Parenteral Medicines, Teva Pharmaceuticals USA, and Teva Sales and
28 Marketing are registered to do business in California with the California Secretary of State.

30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and it is a wholly owned subsidiary of JOHNSON & JOHNSON (“J&J”), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Upon information and belief, J&J is the only company that owns more than 10% of Janssen Pharmaceuticals’ stock, and corresponds with the FDA regarding Janssen’s products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical’s products and Janssen’s profits inure to J&J’s benefit. (together, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as “Janssen”).

31. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including California, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as “Endo”).

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydene, in the United States, including California. In 2012, opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and accounted for 10% of Endo’s total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,

1 oxymorphone, hydromorphone, and hydrocodone products in the United States, including
2 California, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo Medical (SA)
3 International Trade Co., is registered to do business in California with the California Secretary of
4 State.

5 34. ACTAVIS, INC. and WATSON PHARMACEUTICALS, INC. merged in
6 November 2012. The combined company changed its name first to Actavis, Inc. as of January 2013,
7 and then later ACTAVIS PLC in October 2013. ACTAVIS PLC is a wholly owned subsidiary of
8 Teva Ltd. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of
9 business in Parsippany, New Jersey, and is a wholly owned subsidiary of Teva Ltd. ACTAVIS
10 PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business
11 in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS PHARMA,
12 INC. is a wholly owned subsidiary of Teva Ltd. ACTAVIS LLC is a Delaware limited liability
13 company with its principal place of business in Parsippany, New Jersey. ACTAVIS LLC is a
14 wholly owned subsidiary of Teva Ltd. Each of these defendants is owned by Teva Ltd., which uses
15 them to market and sell its drugs in the United States (together, Actavis plc, Actavis, Inc., Actavis
16 LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson
17 Laboratories, Inc. are referred to as “Actavis”).

18 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
19 branded drug Kadian, a generic version of Kadian, and generic versions of Duragesic and Opana,
20 in the United States, including California. Actavis acquired the rights to Kadian from King
21 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009. Watson
22 Laboratories, Inc. and Actavis Pharma, Inc. are registered to do business in California with the
23 California Secretary of State.

24 36. ALLERGAN PLC is a public limited company incorporated in Ireland with its
25 principal place of business in Dublin, Ireland. ALLERGAN, INC. is a Delaware corporation with
26 its principal place of business in Irvine, California and is a wholly owned subsidiary of Allergan
27 plc. ALLERGAN USA, INC. is a Delaware corporation with its principal place of business in
28 Madison, New Jersey and is a wholly owned subsidiary of Allergan plc (together Allergan plc,

1 Allergan, Inc., and Allergan USA, Inc. are referred to as “Allergan”). Allergan manufactures,
2 promotes, sells, and distributes opioids, including the branded drug Norco in the United States,
3 including California. Allergan USA, Inc. and Allergan, Inc. are registered to do business in
4 California with the California Secretary of State.

5 37. Defendant INSYS THERAPEUTICS, INC., is a Delaware corporation with its
6 principal place of business located in Chandler, Arizona.

7 38. Insys manufactures, promotes, sells, and distributes opioids. Insys’ principal source
8 of revenue is Subsys, a Schedule II transmucosal immediate-release formulation of fentanyl in the
9 United States, including California. Subsys was indicated by the FDA for the treatment of
10 breakthrough cancer pain that other opioids could not eliminate.

11 39. In May 2018, an Insys sales representative admitted to taking part in a scheme to
12 bribe physicians with purported speaking fees for marketing and education events in exchange for
13 them prescribing Subsys for off-label uses. Insys’ founder and several other former Insys executives
14 were recently indicted by federal prosecutors on racketeering charges, alleging that these
15 individuals approved and fostered fraudulent behavior against insurance companies and also
16 conspired to bribe practitioners in various states. Insys Group is registered to do business in
17 California with the California Secretary of State.

18 40. MALLINCKRODT, PLC is an Irish public limited company headquartered in
19 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
20 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
21 the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc
22 (together, Mallinckrodt, plc and Mallinckrodt, LLC are referred to as “Mallinckrodt”).

23 41. Mallinckrodt manufactures, markets, and sells drugs in the United States including
24 generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt
25 agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to
26 detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt U.S.
27 Holdings, Mallinckrodt ARD Inc., Mallinckrodt Enterprise Holdings, and Mallinckrodt Hospital
28 Products are registered to do business in California with the California Secretary of State.

42. Collectively, Purdue, Cephalon, Janssen, Endo, Teva, Actavis, Allergan, Insys, and Mallinckrodt are the “Manufacturer Defendants.”

C. The Distributor Defendants

43. CARDINAL HEALTH, INC. (“Cardinal”) is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio.

44. Cardinal distributes prescription opioids to providers and retailers, including in California. Cardinal has engaged in consensual commercial dealings with Alameda County and its residents, and has purposefully availed itself of the advantages of conducting business with and within Alameda County. Cardinal is in the chain of distribution of prescription opioids. Cardinal Health 100, Cardinal Health 127, and Cardinal Health 201 are registered to do business in California with the California Secretary of State.

45. AMERISOURCEBERGEN CORPORATION (“AmerisourceBergen”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania.

46. AmerisourceBergen distributes prescription opioids to providers and retailers, including in California. AmerisourceBergen has engaged in consensual commercial dealings with Alameda County and its residents, and has purposefully availed itself of the advantages of conducting business with and within Alameda County. AmerisourceBergen is in the chain of distribution of prescription opioids. AmerisourceBergen Associate Assistance Fund, AmerisourceBergen Corporation, AmerisourceBergen Drug Corporation, and AmerisourceBergen Services Corporation are registered to do business in California with the California Secretary of State.

47. MCKESSON CORPORATION (“McKesson”) is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San Francisco, California.

48. McKesson distributes prescription opioids to providers and retailers, including in California. McKesson has engaged in consensual commercial dealings with Alameda County and its residents, and has purposefully availed itself of the advantages of conducting business with and

1 within Alameda County. McKesson is in the chain of distribution of prescription opioids.
2 McKesson Corporation is registered to do business in California with the California Secretary of
3 State.

4 49. The data which reveals and/or confirms the identity of the other wrongful opioid
5 distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v.*
6 *U.S. D.O.J.*, 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will
7 voluntarily disclose the data necessary to identify with specificity the transactions which will form
8 the evidentiary basis for the claims asserted herein. *See id.* at 452-53.

9 50. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the
10 market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations
11 listed on the New York Stock Exchange and their principal business consists of the nationwide
12 wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12
13 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen
14 predecessors). Each has been investigated and/or fined by the DEA for the failure to report
15 suspicious orders. Alameda County has reason to believe each has engaged in unlawful conduct
16 which resulted in the distribution, dispensing, and diversion of prescription opioids into Alameda
17 County. Alameda County names each of the "Big 3" herein as defendants and places the industry
18 on notice that Alameda County is acting to abate the public nuisance plaguing its community.
19 Distributor Defendants have had substantial contacts and business relationships with the People.
20 Distributor Defendants have purposefully availed themselves of business opportunities within
21 Alameda County.

22 51. Collectively, AmerisourceBergen, Cardinal, and McKesson are the "Distributor
23 Defendants."

24 **D. The Doe Defendants**

25 52. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
26 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
27 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
28 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff

1 is informed and believes, and on such information and belief alleges, that each of the Defendants
2 named as a DOE is responsible in some manner for the events and occurrences alleged in this
3 Complaint and is liable for the relief sought herein.

4 **III. JURISDICTION AND VENUE**

5 53. This Court has jurisdiction over this action. Defendants are engaging in false and
6 misleading advertising, fraudulent acts, negligent acts, and creating or assisting in the creation of a
7 public nuisance in Alameda County, and the People through their attorneys have the right and
8 authority to prosecute this case on behalf of the People.

9 54. Venue is proper in this Court because Defendants transact business in California and
10 Alameda County, and some of the acts complained of occurred in this venue and the dispute arose
11 in this venue.

12 **IV. GENERAL FACTUAL ALLEGATIONS**

13 **A. An Overview of the Opioid Epidemic**

14 55. The term “opioid” includes all drugs derived from the opium poppy. The United
15 States Food and Drug Administration describes opioids as follows: “Prescription opioids are
16 powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and
17 morphine, among others, and have both benefits as well as potentially serious risks. These
18 medications can help manage pain when prescribed for the right condition and when used properly.
19 But when misused or abused, opioids can cause serious harm, including addiction, overdose, and
20 death.”⁵

21 56. Prescription opioids with the highest potential for addiction are listed under
22 Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives (such
23 as codeine and morphine, also known generally as “opiates”), partially synthetic derivatives (such
24 as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

25 57. Historically, opioids were considered too addictive and debilitating for the treatment
26 of chronic pain such as back pain, migraines, and arthritis. According to Dr. Caleb Alexander,

27
28 ⁵ See U.S. FDA, Opioid Medications, available at <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last accessed December 19, 2017).

1 director of Johns Hopkins University's Center for Drug Safety and Effectiveness, "[opioids] have
2 very, very high inherent risks ... and there's no such thing as a fully safe opioid."⁶

3 58. Opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly
4 over time no longer responds to the drug as strongly as before, thus requiring a higher dose to
5 achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

6 59. Before the 1990s, generally accepted standards of medical practice dictated that
7 opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or
8 for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved
9 patients' ability to overcome pain and function, as well as evidence of *greater* pain complaints as
10 patients developed tolerance to opioids over time, and the serious risk of addiction and other side
11 effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors
12 generally did not prescribe opioids for chronic pain.

13 60. The market for chronic pain patients, however, was much larger, and to take
14 advantage of it, Defendants had to change doctors' general reluctance to prescribe opioids for
15 chronic pain.⁷

16 61. As described herein, Defendants engaged in conduct that directly caused doctors to
17 prescribe skyrocketing amounts of opioids. Defendants also intentionally neglected their
18 obligations to prevent diversion of the highly addictive substance.

19 62. As a result of Defendants' wrongful conduct, the number of opioid prescriptions
20 increased sharply, reaching nearly 250,000,000 prescriptions in 2013, which was almost enough
21 for every person in the United States to have a bottle of pills. This represents an increase of 300%
22 since 1999. In California, opioid prescribing rates peaked in 2013 when 54.9 opioid prescriptions
23 were dispensed per 100 persons.

24 63. Many Americans, including Californians and residents of Alameda County, are now
25

26 ⁶ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
Integrity, available at <https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution> (last accessed December 20, 2017).

27 ⁷ See Harriet Ryan et al., 'You want a description of hell?' *OxyContin's 12-hour problem*, L.A. Times
28 (May 5, 2016), available at <http://www.latimes.com/projects/oxycontin-part1/> (last accessed December 20, 2017).

1 addicted to prescription opioids. In 2016, drug overdoses killed over 60,000 people in the United
 2 States, an increase of more than 22 percent over the previous year. The New York Times reported
 3 in September 2017, that the opioid epidemic is now killing babies and toddlers because deadly
 4 opioids are “everywhere” and are easily mistaken as candy.⁸ The opioid epidemic has been declared
 5 a public health emergency by the President of the United States. The wave of opioid addiction was
 6 created by the increase in prescriptions.

7 64. One in 4 Americans receiving long-term opioid therapy struggles with opioid
 8 addiction. Nearly 2 million Americans have a prescription opioid use disorder. According to the
 9 NIH’s National Institute on Drug Abuse, approximately 21 to 29 percent of patients prescribed
 10 opioids for chronic pain misuse them. Between 8 and 10 percent develop an opioid use disorder.
 11 Four to 6 percent of people who misuse prescription opioids transition to heroin abuse, and about
 12 80 percent of people who use heroin first misused prescription opioids.

13 65. Drug overdose deaths among all Americans increased more than 200 percent
 14 between 1999 and 2015.

15 66. Deaths from prescription opioids have quadrupled in the past 20 years. In California,
 16 there were 4,654 total opioid overdose deaths in 2016.⁹

17 ///

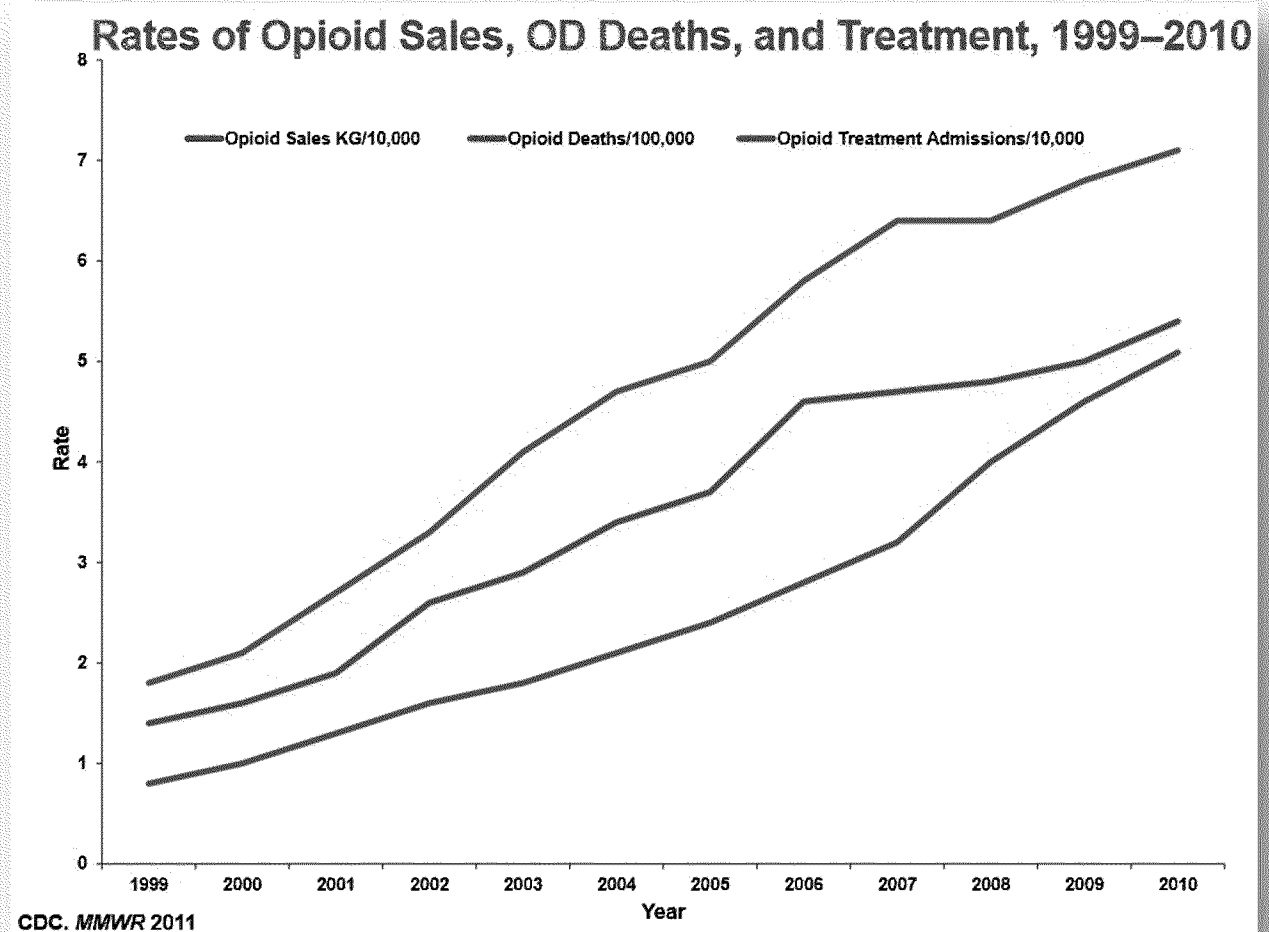
18 ///

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26 ⁸ Julie Turkewitz, “*The Pills are Everywhere: How the Opioid Crisis Claims Its Youngest Victims*, N.Y.
 27 Times (Sept. 20, 2017), available at <https://www.nytimes.com/2017/09/20/us/opioid-deaths-children.html>
 (last accessed January 4, 2018).

28 ⁹ See Center for Disease Control (CDC)/NCHS, National Vital Statistics System, Mortality, available at
<https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last accessed August 13, 2018).

67. At the same time, treatment admissions for abuse of opioids and emergency room visits for non-medical opioid use have dramatically increased. The increases in opioid deaths and treatments are directly tied to the prescribing practices created by Defendants. According to the CDC¹⁰, opioid deaths and treatment admissions are tied to opioid sales:



68. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin, which is pharmacologically similar to prescription opioids. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use. According to the CDC, heroin drug overdose deaths have more than tripled in the past four years. In California, 355 overdose deaths in 2016 involved heroin.¹¹

¹⁰ U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf (last accessed December 29, 2017).

¹¹ See National Institute of Drug Abuse, California Opioid Summary, available at

69. Prescription opioid abuse “is a serious national crisis that affects public health as well as social and economic welfare.” The economic burden of prescription opioid misuse alone on the public is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.¹²

B. The Manufacturer Defendants Spread False or Misleading Information About the Safety of Opioids

70. Each Manufacturer Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain without risk of abuse or addiction, resulting in opioid prescriptions to a far larger group of patients who are much more likely to become addicted. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids.

71. The Manufacturer Defendants employed the same marketing plans and strategies, and deployed the same messages in and around California, including in Alameda County, as they did nationwide. Across the pharmaceutical industry, corporate headquarters are responsible for funding and overseeing “core message” development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their prescription drugs.

72. To increase the impact of their deceptive marketing schemes, on information and belief, the Manufacturer Defendants coordinated and created unified marketing plans to ensure that their messages were consistent with one another and effective across all their marketing efforts.

73. The deceptive marketing schemes included, among others: (a) false or misleading direct, branded advertisements; (b) false or misleading direct-to-physician marketing, also known

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/california-opioid-summary>, (last accessed August 13, 2018).

¹² Opioid Crisis, NIH, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis> (last accessed December 19, 2017).

1 as “detailing;” (c) false or misleading materials, speaker programs, webinars, and brochures; and
 2 (d) false or misleading unbranded advertisements or statements by purportedly neutral third parties
 3 that were really designed and distributed by the Manufacturer Defendants. All of these schemes
 4 were geared towards convincing both doctors and patients that opioid use to treat chronic pain
 5 carried a low, or no, risk of addiction.

6 74. Contrary to the language on their drugs’ labels regarding the serious risks associated
 7 with their use, the Manufacturer Defendants made false and misleading claims that: (a) downplayed
 8 the serious risk of addiction; (b) created and promoted the concept of “pseudoaddiction” when signs
 9 of actual addiction began appearing, and advocated that the signs of addiction should be treated
 10 with more opioids; (c) exaggerated the effectiveness of screening tools to prevent addiction; (d)
 11 claimed that opioid dependence and withdrawal are easily managed; (e) denied the risks of higher
 12 dosages; and (f) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent
 13 abuse and addiction. The Manufacturer Defendants also falsely touted the benefits of long-term
 14 opioid use, including the supposed ability of opioids to improve function and quality of life, even
 15 though there was no scientifically reliable evidence to support the Manufacturer Defendants’
 16 claims.

17 75. These statements were not only unsupported by or contrary to the scientific
 18 evidence, but they also were contrary to pronouncements by and guidance from the FDA and CDC
 19 based on that exact same evidence. Indeed, as discussed herein, the 2016 CDC Guideline makes it
 20 patently clear that the Manufacturer Defendants’ schemes were and continue to be deceptive.

21 76. The Manufacturer Defendants began their marketing schemes decades ago and
 22 continue them today.

23 77. The Manufacturer Defendants’ efforts have been wildly successful. Opioids are now
 24 the most prescribed class of drugs. Globally, opioid sales generated \$1.1 billion in revenue for drug
 25 companies in 2010 alone, and sales in the United States have exceeded \$8 billion in revenue
 26 annually since 2009.¹³ In an open letter to the nation’s physicians in August 2016, the U.S. Surgeon

27
 28 ¹³ See Katherine Eban, *Oxycontin: Purdue Pharma’s Painful Medicine*, Fortune, (Nov. 9, 2011); David Crow, *Drugmakers Hooked on 10bn Opioid Habit*, Fin. Times (August 10, 2016).

1 General expressly connected this “urgent health crisis” to “heavy marketing of opioids to doctors.
2 . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed
3 for legitimate pain.”¹⁴

4 78. On information and belief, as a part of their deceptive marketing schemes, the
5 Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient
6 populations in the United States, including California.

7 79. For example, on information and belief, the Manufacturer Defendants focused their
8 deceptive marketing schemes on primary care doctors, who were more likely to treat chronic pain
9 patients and prescribe them drugs, but who were less likely to be well-schooled in treating pain and
10 the risks and benefits of opioids, including abuse and addiction, and therefore more likely to accept
11 the Manufacturer Defendants’ misrepresentations.

12 80. On information and belief, the Manufacturer Defendants also targeted vulnerable
13 patient populations like the elderly and veterans, who tend to suffer from chronic pain.

14 81. The Manufacturer Defendants targeted these vulnerable patients even though the
15 risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC
16 Guideline observed that existing evidence showed that elderly patients taking opioids suffer from
17 elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse
18 drug effects and interactions. The Guideline therefore concluded that there are special risks of long-
19 term opioid use for elderly patients and recommended that doctors use “additional caution and
20 increased monitoring” to minimize the risks of opioid use in elderly patients. The same is true for
21 veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress
22 disorder, which interact dangerously with opioids.

23 82. The Manufacturer Defendants intentionally continued their conduct, as alleged
24 herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms
25 and damages alleged herein.

26
27
28 ¹⁴ Murthy, supra note 3.

1 **1. The Manufacturer Defendants Engaged in False and Misleading Direct**
 2 **Marketing of Opioids**

3 83. Each Manufacturer Defendant conducted, and continues to conduct, direct
 4 marketing consisting of advertising campaigns touting the purported benefits of their branded
 5 drugs. For example, upon information and belief, the Manufacturer Defendants spent more than
 6 \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

7 84. A number of the Manufacturer Defendants' branded ads deceptively portrayed the
 8 benefits of opioids for chronic pain. For example:

- 9 a. Endo, on information and belief, has distributed and made available on its website
 10 opana.com a pamphlet promoting Opana ER with photographs depicting patients
 11 with physically demanding jobs like construction worker and chef, misleadingly
 12 implying that the drug would provide long-term pain-relief and functional
 13 improvement.
 14 b. On information and belief, Purdue also ran a series of ads, called "Pain vignettes,"
 15 for OxyContin in 2012 in medical journals. These ads featured chronic pain
 16 patients and recommended OxyContin for each. One ad described a "54-year-old
 17 writer with osteoarthritis of the hands" and implied that OxyContin would help the
 18 writer work more effectively.

19 85. Although Endo and Purdue agreed in late 2015 and 2016 to cease making these
 20 misleading representations in New York, they continued to disseminate them elsewhere throughout
 21 the United States, including California.

22 86. The direct advertising disseminated by the Manufacturer Defendants failed to
 23 disclose studies that were not favorable to their products, or that they lacked clinical evidence to
 24 support many of their claims.

25 **2. The Manufacturer Defendants Used Detailing and Speaker Programs**
 26 **to Spread False and Misleading Information About Opioids**

27 87. Each Manufacturer promoted the use of opioids for chronic pain through
 28 "detailers"—sophisticated and specially trained sales representatives who visited individual doctors
 and medical staff in their offices—and small group speaker programs.

88. The Manufacturer Defendants invested heavily in promoting the use of opioids for
 chronic pain through detailers and small group speaker programs.

89. The Manufacturer Defendants devoted massive resources to direct sales contacts with doctors via detailers. Upon information and belief, the Manufacturer Defendants spend in excess of \$168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000. From mid-2013 through 2015, Purdue, Janssen, and Endo detailed at least 6,238, 584, and 195 prescribers in California respectively. By itself, Purdue was responsible for more than 1 out of every 3 reported opioid-related detailing visits in California by Defendants.

90. On information and belief, these detailers have spread and continue to spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors, including thousands of doctors in California, in the following manner:

- a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- b. Describe their opioid products as “steady state” – falsely implying that these products are less likely to produce the high and lows that fuel addiction – or as less likely to be abused or result in addiction;
- c. Tout the effectiveness of screening or monitoring patients as a strategy for managing opioid abuse and addiction;
- d. State that there is no maximum dose and that doctors can safely increase doses without disclosing the significant risks to patients at higher doses;
- e. Discuss “pseudoaddiction;”
- f. State that patients would not experience withdrawal if they stopped using their opioid products; and
- g. State that abuse-deterrent formulations are tamper- or crush-resistant and harder to abuse or misuse.

91. Because these detailers must adhere to scripts and talking points drafted by the Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the Manufacturer Defendants’ detailers made and continue to make these misrepresentations to the thousands of California doctors they have visited and continue to visit. The Manufacturer Defendants have not corrected this misinformation.

92. The Manufacturer Defendants’ detailing to doctors was highly effective in generating the national proliferation of prescription opioids. On information and belief, the Manufacturer Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual

1 targeting, customizing, and monitoring of their marketing efforts.

2 93. The Manufacturer Defendants also identified doctors to serve on their speakers'
3 bureaus in exchange for payment and other remuneration, as well as attend programs with speakers
4 and meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
5 they were providing unbiased and medically accurate presentations when they were in fact
6 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
7 presentations conveyed misleading information, omitted material information, and failed to correct
8 the Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids,
9 including addiction risks.

10 94. Each Manufacturer Defendant devoted and continues to devote massive resources
11 to direct sales contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing
12 branded opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000.
13 The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$10 million by Endo,
14 and \$2 million by Actavis.

15 95. Marketing impacts prescribing habits, with face-to-face detailing having the greatest
16 influence. On information and belief, more frequent prescribers are generally more likely to have
17 received a detailing visit, and in some instances, more infrequent prescribers of opioids received a
18 detailing visit from a Manufacturer Defendant's detailer and then prescribed only that Manufacturer
19 Defendant's opioid products.

20 96. The FDA has cited at least one Manufacturer Defendant for deceptive promotions
21 used by its detailers and in its direct-to-physician marketing. In 2010, the FDA notified Actavis that
22 certain brochures distributed by Actavis were "false or misleading because they omit and minimize
23 the serious risks associated with [Kadian], broaden and fail to present the limitations to the
24 approved indication of the drug, and present unsubstantiated superiority and effectiveness claims."
25 The FDA also found that "[t]hese violations are a concern from a public health perspective because
26 they suggest that the product is safer and more effective than has been demonstrated."¹⁵

27
28 ¹⁵ Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug
Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at

1 **3. The Manufacturer Defendants Deceptively Marketed Opioids through**
 2 **Seemingly Independent Third Parties that Disseminated Unbranded**
 3 **Advertising Created by the Manufacturer Defendants**

4 97. The Manufacturer Defendants also deceptively marketed opioids in California
 5 through unbranded advertising—i.e., advertising that promotes opioid use generally but does not
 6 name a specific opioid. This type of advertising was ostensibly created and disseminated by
 7 independent third parties. But by funding, directing, reviewing, editing, and distributing unbranded
 8 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
 9 disseminated by these third parties and acted in concert with them to falsely and misleadingly
 10 promote opioids for the treatment of chronic pain as non-addictive.

11 98. The extent of the financial ties between the opioid industry and third-party advocacy
 12 groups is stunning. A recent report released by the United State Senate Homeland Security and
 13 Governmental Affairs Committee reveals nearly \$9 million in payments from companies, including
 14 Purdue and Janssen, to 14 outside groups between 2012 and 2017.¹⁶ According to the report, “[t]he
 15 fact that ... manufacturers provided millions of dollars to the groups described below suggests, at
 16 the very least, a direct link between corporate donations and the advancement of opioids-friendly
 17 messaging.” The report concluded that “many of the groups described in this report may have
 18 played a significant role in creating the necessary conditions for the U.S. opioids epidemic.”

19 99. The Manufacturer Defendants utilized third-party, unbranded advertising to market
 20 opioids to avoid regulatory scrutiny because such advertising is not submitted to and typically is
 21 not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded
 22 advertising to give the false appearance that the deceptive messages came from an independent and
 23 therefor objective source. Like tobacco companies did before them, the Manufacturer Defendants
 24 used third parties that they funded, directed, and controlled to carry out and conceal their scheme

25 _____
 26 <http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed December
 29, 2017).

27 ¹⁶ See Scott Neuman & Alison Kodjak, *Drugmakers Spend Millions Promoting Opioids To Patient*
 28 *Groups, Senate Report Says*, NPR.org (Feb. 13, 2018), available at <https://www.npr.org/sections/thetwo-way/2018/02/13/585290752/drugmakers-spent-millions-promoting-opioids-to-patient-groups-senate-report-says> (last accessed February 23, 2018).

1 to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

2 100. The Manufacturer Defendants’ deceptive, third-party, unbranded advertising often
3 contradicted what they said in their branded materials reviewed by the FDA. For example, Endo’s
4 unbranded advertising stated that “People who take opioids as prescribed usually do not become
5 addicted.” This directly contradicted its concurrent, branded advertising for Orpana ER, which
6 warned that “use of opioid analgesic products carries the risk of addiction even under appropriate
7 medical use.”

8 101. In addition to using third parties to disguise the source of their misinformation
9 campaign, the Manufacturer Defendants also retained the services of a small group of physicians—
10 known as “key opinion leaders” or “KOLs”—to convince both doctors and patients that opioid use
11 to treat chronic pain carried a low, or no, risk of addiction. On information and belief, the
12 Manufacturer Defendants’ KOLS were selected, funded, and elevated by the Manufacturer
13 Defendants because their public positions supported the use of opioids to treat chronic pain.

14 102. Manufacturer Defendants paid these KOLs to serve as consultants or on their
15 advisory boards and to give talks or present continuing medical education programs (CMEs), and
16 their support helped these KOLs become respected industry experts. As they rose to prominence,
17 these KOLs touted the benefits of opioids to treat chronic pain without significant risk of addiction,
18 repaying Defendants by advancing their marketing goals. These KOLs’ professional reputations
19 became dependent on continuing to promote a pro-opioid message.

20 103. Pro-opioid doctors like the KOLs are one of the most important avenues that the
21 Manufacturer Defendants use to spread their false and misleading statements about the risks and
22 benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely heavily and
23 more uncritically on their peers for guidance, and KOLs provide the false appearance of unbiased
24 and reliable support for treatment of chronic pain through chronic opioid therapy without
25 significant risk of addiction.

26 104. For example, the New York Attorney General (“NY AG”) found in its settlement
27 with Purdue that through March 2015, the Purdue website *In the Face of Pain* failed to disclose
28

1 that doctors who provided testimonials on the site were paid by Purdue,¹⁷ and concluded that
2 Purdue's failure to disclose these financial connections potentially misled consumers regarding the
3 objectivity of the testimonials.

4 105. The Manufacturer Defendants' KOLs have written, consulted on, edited, and lent
5 their names to books and articles, and given speeches and CMEs supportive of chronic opioid
6 therapy while minimizing risks of addiction. Manufacturer Defendants also created opportunities
7 for their KOLs to participate in research studies Manufacturer Defendants suggested or chose and
8 then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did
9 not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
10 opioid therapy that acknowledged risks of addiction.

11 106. The Manufacturer Defendants' KOLs also served on committees that developed
12 treatment guidelines that strongly encourage the use of opioids to treat chronic pain and on the
13 boards of pro-opioid advocacy groups and professional societies that develop, select, and present
14 CMEs. These guidelines and CMEs were not supported by the scientific evidence at the time they
15 were created, and they are not supported by the scientific evidence today. Defendants were able to
16 direct and exert control over each of these activities through their KOLs. Notably, the 2016 CDC
17 Guideline recognizes that treatment guidelines can "change prescribing practices."

18 107. Pro-opioid KOLs have admitted to making false claims about the effectiveness of
19 opioids. For example, Dr. Russell Portenoy received research support, consulting fees, and other
20 compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
21 subsequently admitted that he "gave innumerable lectures ... about addictions that weren't true."
22 His lectures as a pro-opioid KOL falsely claimed that fewer than 1 percent of patients would
23 become addicted to opioids, but Dr. Portenoy later admitted that the primary goal was to
24 "destigmatize" opioid. Dr. Portenoy conceded that "[d]ata about the effectiveness of opioids does
25

26 ¹⁷ See New York State Office of the Attorney General, *A.G. Schneiderman Announces Settlement with*
27 *Purdue Pharma That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By*
28 *The Manufacturer* (August 20, 2015), available at <https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent> (last accessed December 20, 2017).

1 not exist.” According to Dr. Portenoy, “Did I teach about pain management, specifically about
2 opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did.” Dr. Portenoy
3 admitted that “[i]t was clearly the wrong thing to do.”¹⁸

4 108. Dr. Portenoy also made frequent media appearances promoting opioids and
5 spreading misrepresentation, such as his claim “the likelihood that the treatment of pain using an
6 opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He even
7 appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic
8 pain. On this widely-watched program broadcast across the country, Dr. Portenoy claimed:
9 “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a
10 personal history, of substance abuse, and does not have a history in the family of substance abuse,
11 and does not have a very major psychiatric disorder, most doctors can feel very assured that the
12 person is not going to become addicted.”¹⁹

13 109. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director
14 of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr.
15 Webster was President of the American Academy of Pain Medicine (“AAPM”) in 2013. (He also
16 is a Senior Editor of Pain Medicine, which is the same journal that published the Endo special
17 advertising supplements touting Opana ER.) Dr. Webster was the author of numerous CMEs
18 sponsored by Cephalon, Endo and Purdue, which advocated the use of chronic opioid therapy. At
19 the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants,
20 including nearly \$2 million from Cephalon.

21 110. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, which is a five-
22 question, one-minute screening tool relying on patient self-reports that purportedly allows doctors
23 to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability
24 to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to
25 prescribe opioids long-term, and, for this reason, references to screening appear in various industry
26

27 ¹⁸ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J. (Dec. 17,
28 2012), available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>
(last accessed December 20, 2017).

¹⁹ Good Morning America (ABC television broadcast Aug. 30, 2010).

1 supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to,
2 websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias
3 underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into
4 their own guidelines, indicating their reliance on the Manufacturer Defendants and those under
5 their influence and control.

6 111. In 2011, Dr. Webster presented a webinar program sponsored by Purdue entitled
7 "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended
8 use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of
9 prescriptions" and "overdose deaths." This webinar was available to and was intended to reach
10 doctors in Alameda County and doctors treating residents of Alameda County.²⁰

11 112. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction,"
12 which is the notion that addictive behaviors should be seen as indications of undertreated pain and
13 not a warning. In Dr. Webster's description, the only way to differentiate the two was to increase a
14 patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid*
15 *Abuse While Managing Pain*—a book that remains available online—when faced with signs of
16 aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response."²¹
17 Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster
18 reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse
19 to give patients more medication."²²

20 113. On information and belief, the Manufacturer Defendants also entered into
21 arrangements with seemingly unbiased and independent patient and professional organizations to
22 promote opioids for the treatment of chronic pain. Under the direction and control of the
23 Manufacturer Defendants, these "Front Groups"—which include, but are not limited to, the
24 American Pain Foundation ("APF")²³ and the American Academy of Pain Medicine—generated

25 _____
26 ²⁰ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
available at http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_content&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

27 ²¹ Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

28 ²² John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, (Feb. 18, 2012).

²³ Dr. Portenoy was a member of the board of the APF.

1 treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. The
2 evidence did not support these guidelines, materials, and programs at the time they were created,
3 and the scientific evidence does not support them today. Indeed, they stand in marked contrast to
4 the 2016 CDC Guideline.

5 114. The Manufacturer Defendants worked together through Front Groups to spread their
6 deceptive messages about the risks and benefits of long-term opioid therapy. Indeed, the
7 Manufacturer Defendants spent millions on the Front Groups to generate false opioid-friendly
8 messaging.²⁴ The amount of industry funding, and its sources, is obscured by a lack of transparency
9 on behalf of both the opioid industry and the Front Groups.

10 115. On information and belief, these Front Groups also assisted the Manufacturer
11 Defendants by responding to negative articles, advocating against regulatory or legislative changes
12 that would limit opioid prescribing in accordance with the scientific evidence, and conducting
13 outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

14 116. These Front Groups depended on the Manufacturer Defendants for funding and, in
15 some cases, for their very survival. On information and belief, the Manufacturer Defendants
16 exercised control over programs and materials created by these groups by collaborating on, editing,
17 and approving their content, and by funding their dissemination. In doing so, the Manufacturer
18 Defendants made sure that the Front Groups would only generate messages the Manufacturer
19 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
20 experts serving the needs of their members, whether patients suffering from pain or doctors treating
21 those patients.

22 117. In particular, Cephalon, Endo, Janssen, and Purdue utilized many Front Groups,
23 including many of the same ones. Several of the most prominent Front Groups are described in
24 greater detail below, but there are many others, including the American Pain Society, American
25 Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association,
26 the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.²⁵

27
28 ²⁴ See Neuman & Kodjack, *supra* note 16.

²⁵ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E.

118. Organizations, including the U.S. Senate Finance Committee, began to investigate the American Pain Foundation (“APF”) in 2012 to determine the links, financial and otherwise, between APF and the opioid industry.²⁶ The investigation revealed that APF received 90 percent of its funding from the drug and medical-device industry, and “its guides for patients, journalists and policymakers had played down the risks associated with opioid painkillers while exaggerating the benefits from the drugs.” Within days, APF dissolved “due to irreparable economic circumstances.”

119. Another one of the Front Groups for the Manufacturer Defendants was the American Academy of Pain Medicine (“AAPM”). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants’ deceptive marketing of chronic opioid therapy.

120. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an “exclusive venue” for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended these annual events.

121. On information and belief, AAPM is viewed internally by Endo as “industry friendly,” with Endo advisors and speakers among its active members. Endo attended AAPM

Price, U.S. Dep’t of Health and Human Servs., (May 5, 2015).

²⁶ Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies Ties to Pain Groups*, Wash. Post (May 8, 2012), available at https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIQA2X4qBU_story.html (last accessed December 19, 2017).

1 conferences, funded its CMEs, and distributed its publications. The conferences sponsored by
2 AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone.
3 AAPM’s presidents have included top industry-supported KOLs like Lynn Webster and Perry Fine
4 of the University of Utah. Dr. Webster was even elected as AAPM’s president while under DEA
5 investigation.

6 122. The Manufacturer Defendants were able to influence AAPM through both their
7 significant and regular funding and the leadership of pro-opioid KOLs within the organization.

8 123. In 1996, AAPM and APS jointly issued a consensus statement entitled “The Use of
9 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain while
10 claiming that the risk of a patient’s addiction to opioids was low. Dr. Haddox, who co-authored the
11 AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole
12 consultant. The consensus statement remained on AAPM’s website until 2011, and upon
13 information and belief, was taken down from AAPM’s website only after a doctor complained.²⁷

14 124. AAPM and APS issued their own guidelines in 2009 (“AAPM/APS Guidelines”)
15 and continued to recommend the use of opioids to treat chronic pain while minimizing the risk of
16 addiction.²⁸ Treatment guidelines like these have been relied upon by doctors, especially the
17 general practitioners and family doctors targeted by the Manufacturer Defendants, to prescribe
18 opioids to treat chronic pain. Treatment guidelines not only directly inform doctors’ prescribing
19 practices, but they also are cited throughout the scientific literature and referenced by third-party
20 payors in determining whether they should cover treatments for specific indications.
21 Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment
22 guidelines with doctors during individual sales visits.

23 125. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines,
24 including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen, Cephalon, Endo,
25 and Purdue. The 2009 AAPM/APS Guidelines promote opioids as “safe and effective” for treating
26

27 ²⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American
Academy of Pain Medicine and the American Pain Society*, 13 *Clinical J. Pain* 6 (1997).

28 ²⁸ Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer
Pain*, 10 *J. Pain* 113 (2009).

1 chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is
 2 manageable for patients regardless of past abuse histories.²⁹ One panel member, Dr. Joel Saper,
 3 Clinical Professor of Neurology at Michigan State University and founder of the Michigan
 4 Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009
 5 AAPM/APS Guidelines were influenced by contributions from drug companies, including
 6 Manufacturer Defendants, to the sponsoring organizations and committee members. The 2009
 7 AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced
 8 not only treating physicians, but also the body of scientific evidence on opioids. The 2009
 9 AAPM/APS Guidelines have been cited hundreds of times in academic literature, were
 10 disseminated in Alameda County during the relevant time period, are still available online, and
 11 were often reprinted in the Journal of Pain, which is the official journal of the American Pain
 12 Society. The Manufacturer Defendants widely referenced and promoted the 2009 AAPM/APS
 13 Guidelines without disclosing the lack of evidence to support their conclusions or the Manufacturer
 14 Defendants' financial support to members of the panel.

15 126. On information and belief, the Manufacturer Defendants combined their efforts
 16 through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised
 17 of representatives from opioid manufacturers (including Endo, Janssen, and Purdue) and various
 18 Front Groups, almost all of which received substantial funding from the Manufacturer Defendants.
 19 Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids
 20 was not unacceptably negative and did not require mandatory participation by prescribers. PCF also
 21 worked to address a lack of coordination among its members and develop cohesive industry
 22 messaging.

23 127. On information and belief, through Front Groups and KOLs, the Manufacturer
 24 Defendants wrote or influenced prescribing guidelines that reflected the messaging the
 25 Manufacturer Defendants wanted to promote rather than scientific evidence regarding dangers of
 26 addiction.

27
 28 ²⁹ *Id.*

128. Through these means, and likely others still concealed, the Manufacturer Defendants collaborated to spread deceptive messages about the risks and benefits of long-term opioid use.

C. The Manufacturer Defendants' Statements about the Safety of Opioids Were Patently False

129. To convince doctors and patients that opioids carry a low risk of addiction, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that the FDA and CDC conclusively debunked.

130. These misrepresentations reinforced each other and created the dangerously misleading impressions, among others, that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive.

131. Some examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by Manufacturing Defendants, include:

- a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggests that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative prescriptions, or theft. This publication remains available today.³⁰

³⁰ Available at <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed December 19, 2017).

- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo and Cephalon distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that “[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website www.opana.com.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” This guide is still available online.
- f. Janssen currently runs a website, *Prescriberresponsibly.com* (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”³¹
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “misconceptions about opioid addiction[.]” This publication is still available online.³²
- h. Detailers for the Manufacturer Defendants in California have minimized or omitted and continue to minimize or omit any discussion with doctors or their medical staff in California, including in Alameda County, about the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

132. The Manufacturer Defendants engaged in this campaign of misinformation in an intentional effort to deceive doctors and patients and thereby increase the use of their opioid products.

133. The Manufacturer Defendants’ misrepresentations have been conclusively debunked by the FDA and CDC, and are contrary to longstanding scientific evidence.

134. As noted in the 2016 CDC Guideline³³ endorsed by the FDA, there is “extensive

³¹ Available at, <http://www.prescriberresponsibly.com/articles/opioid-pain-management> (last accessed December 19, 2017).

³² Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 20, 2017).

³³ Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*,

evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication use presents serious risks, including ... opioid use disorder” and that “continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder.”

135. The FDA further exposed the falsity of Defendants’ claims about the low risk of addiction when it announced changes to the labels for extended-release/long-acting opioids in 2013 and for immediate-release opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘*high potential for abuse*’” and that opioids “are associated with a *substantial risk of misuse*, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.)³⁴ According to the FDA, because of the “*known* serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, *even at recommended doses*, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients appropriately prescribed [opioids].”

136. The Manufacturer Defendants have been and are aware that their misrepresentations about opioids are false.

137. In a 2016 settlement agreement with Endo, the NY AG found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”³⁵ While Endo claimed until at least April 2012 on its

Morbidity & Mortality Wkly Rep. (Mar. 18, 2016) [hereinafter 2016 CDC Guideline], available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last accessed December 20, 2017).

³⁴ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.d., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP (Mar. 22, 2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed December 19, 2017).

³⁵ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 61525999.3

www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” the NY AG found that Endo had no evidence for that statement. Consistent with this finding, Endo agreed not to “make statements that ... opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. This prohibition did not extend to California.

138. The Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Drs. Portenoy and Webster—and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims that were made by, and are continuing to be made by Defendants are described below:

- a. Cephalon, Endo, and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online.³⁶
- b. On information and belief, Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is *under-treated* . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug- seeking behaviors] in patients who have pain that has not been effectively treated.”

15-228), at 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed December 19, 2017).

³⁶ See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse” in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long acting opioid.
- f. Details for Purdue have directed doctors and their medical staffs in California, including in Alameda County, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.
- g. Purdue and Cephalon sponsored APF’s Treatment Options: A Guide for People Living with Pain (2007), which states: “Pseudo-addiction describes patient behaviors that may occur when pain is undertreated...Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.”

Deceptive Claims of Pseudoaddiction

139. The concept of pseudoaddiction is fictional. The 2016 CDC Guideline rejects pseudoaddiction and does not recommend that opioid dosages be increased if a patient is not experiencing pain relief. Instead, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

140. In connection with its 2016 settlement with the NY AG, Endo was forced to admit that the concept of pseudoaddiction was a sham. Indeed, the NY AG found that “[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents” and reported that despite the fact that Endo trained its sales representative to use the concept of pseudoaddiction, “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”³⁷ Consistent with the NY AG’s conclusions, Endo agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York. Endo made no such agreement

³⁷ See *supra* note 35, at 7.

1 with respect to California.

2 141. The Manufacturer Defendants also falsely instructed doctors and patients that
3 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
4 them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These
5 misrepresentations were especially insidious because the Manufacturer Defendants aimed them at
6 general practitioners and family doctors who lack the time and expertise to closely manage higher-
7 risk patients on opioids. The Manufacturer Defendants' misrepresentations made these doctors feel
8 more comfortable prescribing opioids to their patients, and patients more comfortable starting on
9 opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were
10 made by, and are continuing to be made by Defendants after March 21, 2011, are described below:

- 11 a. On information and belief, Endo paid for a 2007 supplement in the *Journal of*
12 *Family Practice* written by a doctor who became a member of Endo's speakers
13 bureau in 2010. The supplement, entitled *Pain Management Dilemmas in*
14 *Primary Care: Use of Opioids*, emphasized the effectiveness of screening
tools, claiming that patients at high risk of addiction could safely receive
chronic opioid therapy using a "maximally structured approach" involving
toxicology screens and pill counts.
- 15 b. On information and belief, Purdue sponsored a November 2011 webinar,
16 *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed
that screening tools, urine tests, and patient agreements prevent "overuse of
prescriptions" and "overdose deaths."
- 17 c. On information and belief, as recently as 2015, Purdue has represented in
18 scientific conferences that "bad apple" patients – and not opioids – are the
19 source of the addiction crisis and that once those "bad apples" are identified,
doctors can safely prescribe opioids without causing addiction.
- 20 d. On information and belief, detailers for the Manufacturer Defendants have
21 touted and continue to tout to doctors in California, including Alameda County
the reliability and effectiveness of screening or monitoring patients as a tool
for managing opioid abuse and addiction.

22 142. Once again, the 2016 CDC Guideline confirms that these types of statements were
23 false, misleading, and unsupported at the time they were made by the Manufacturer Defendants.
24 The 2016 CDC Guideline notes that there are *no* studies assessing the effectiveness of risk
25 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill counts
26 widely believed by doctors to detect and deter abuse—"for improving outcomes related to
27 overdose, addiction, abuse, or misuse." As a result, the 2016 CDC Guideline recognizes that
28

1 available risk screening tools “show *insufficient accuracy* for classification of patients as at low or
2 high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
3 ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

4 143. To underplay the risk and impact of addiction and make doctors feel more
5 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that opioid
6 dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and
7 failed to disclose the increased difficulty of stopping opioids after long-term use.

8 144. For example, on information and belief, a 2011 non-credit educational program
9 sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms
10 can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.

11 145. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
12 *Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated
13 by gradually decreasing the dose of medication during discontinuation” without mentioning any
14 hardships that might occur.³⁸ This publication was available on APF’s website until the
15 organization dissolved in May 2012.

16 146. Detailers for Janssen have told and continue to tell doctors in California, including
17 Alameda County, that their patients would not experience withdrawal if they stopped using opioids.

18 **Deceptive Minimization of Opioid Withdrawal**

19 147. The Manufacturer Defendants also deceptively minimized the significant symptoms
20 of opioid withdrawal—described in the 2016 CDC Guideline as including drug craving, anxiety,
21 insomnia, abdominal pain, vomiting, diarrhea, tremor, and rapid heartbeat—and grossly
22 understated the difficulty of tapering, particularly after long-term opioid use.

23 148. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC Guideline
24 recognizes that the duration of opioid use and the dosage of opioids prescribed should be “limit[ed]”
25 to “minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,”
26 because “physical dependence on opioids is an expected physiologic response in patients exposed

27 _____
28 ³⁸ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed
December 19, 2017).

1 to opioids for *more than a few days.*” (Emphasis added.) The 2016 CDC Guideline states that
 2 “more than a few days of exposure to opioids significantly increases hazards” and “each day of
 3 unnecessary opioid use increases likelihood of physical dependence without adding benefit.” The
 4 2016 CDC Guideline further states that “tapering opioids can be especially challenging after years
 5 on high dosages because of physical and psychological dependence” and highlights the difficulties,
 6 including the need to carefully identify “a taper slow enough to minimize symptoms and signs of
 7 opioid withdrawal” and to “pause[] and restart[]” tapers depending on the patient’s response. The
 8 CDC also acknowledges the lack of any “high-quality studies comparing the effectiveness of
 9 different tapering protocols for use when opioid dosage is reduced or opioids are discontinued.”

10 **Deceptive Claims that Opioid Dosages Could Be Increased without Added Risk**

11 149. The Manufacturer Defendants also falsely claimed that doctors and patients could
 12 increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to
 13 patients at higher dosages. The ability to escalate dosages was critical to the Manufacturer
 14 Defendants’ efforts to market opioids for long-term use to treat chronic pain because, absent this
 15 misrepresentation, doctors would have abandoned treatment when patients built up tolerance and
 16 lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that
 17 were made by, and are continuing to be made by Defendants, are described below:

- 18 a. On information and belief, Actavis’s predecessor created a patient brochure for
 19 Kadian in 2007 that stated, “Over time, your body may become tolerant of
 20 your current dose. You may require a dose adjustment to get the right amount
 21 of pain relief. This is not addiction.” Upon information and belief, based on
 22 Actavis’ acquisition of its predecessor’s marketing materials along with the
 23 rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- 24 b. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for*
 25 *People Living with Pain* (2007), which claims that some patients “need” a
 26 larger dose of an opioid, regardless of the dose currently prescribed. The guide
 27 stated that opioids have “no ceiling dose” and are therefore the most
 28 appropriate treatment for severe pain. This guide is still available online.³⁹
- 29 c. Endo sponsored a website, “PainKnowledge,” which, upon information and
 30 belief, claimed in 2009 that opioid dosages may be increased until “you are on
 31 the right dose of medication for your pain.”

³⁹ Available at, <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last
 accessed December 19, 2017).

- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120), on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased... You won't 'run out' of pain relief."⁴⁰
- e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. On information and belief, through March 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.⁴¹
- h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.⁴²
- j. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdoses.
- k. On information and belief, Purdue's detailers have told doctors in California, including in Alameda County that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

150. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explained in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explained that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC

⁴⁰ Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

⁴¹ Available at, <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed December 19, 2017).

⁴² Brief of the APF et al. in support of Appellant, *United States v. Hurowitz*, No. 05-4474, at 9 (4th Cir. Sept. 8, 2005).

1 also stated that there are “increased risks for opioid use disorder, respiratory depression, and death
2 at higher dosages.” This is why the CDC advised doctors to “avoid increasing dosages” above 90
3 morphine milligram equivalents per day.

4 151. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In
5 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing
6 opioid dose and risk of certain adverse events.” For example, the FDA noted that studies “appear
7 to credibly suggest a positive association between high-dose opioid use and the risk of overdose
8 and/or overdose mortality.” In fact, a recent study found that 92% of persons who died from an
9 opioid-related overdose were initially prescribed opioids for chronic pain.

10 **Deceptive Advertising of Abuse Deterrent Opioids**

11 152. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-deterrent
12 properties of some of their opioid formulations also has created false impressions that these opioids
13 can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care
14 physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less
15 addictive.

16 153. These abuse deterrent formulations (AD opioids) purportedly: (a) are harder to
17 crush, chew, or grind; (b) become gelatinous when combined with a liquid, making them harder to
18 inject; or (c) contain a counteragent such as naloxone that is activated if the tablets are tampered.
19 Despite this, AD opioids can be defeated—often quickly and easily—by those determined to do so.
20 The 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent
21 technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the
22 technologies—even when they work—do not prevent opioid abuse through oral intake, the most
23 common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do *not*
24 reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term
25 as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the
26 Director of the CDC, has further reported that his staff could not find “any evidence showing the
27
28

1 updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”⁴³

2 154. Because of these significant limitations on AD opioids, as well as the heightened
3 risk for misconceptions and the false belief that AD opioids can be prescribed safely, the FDA has
4 cautioned that “[a]ny communications from the sponsor companies regarding AD properties must
5 be truthful and not misleading (based on a product’s labeling), and supported by sound science
6 taking into consideration the totality of the data for the particular drug. Claims for AD opioid
7 products that are false, misleading, and/or insufficiently proven do not serve the public health.”

8 155. Despite this lack of evidence, the Manufacturer Defendants have made and continue
9 to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations
10 to prevent or reduce abuse and addiction and the safety of these formulations.

11 156. For example, Endo has marketed Opana ER⁴⁴ as tamper- or crush-resistant and less
12 prone to misuse and abuse even though: (a) the FDA rejected Endo’s petition to approve Orpana
13 ER as abuse-deterrent in 2012; (b) the FDA warned in a 2013 letter that there was *no* evidence that
14 Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (c) Endo’s own
15 studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.
16 Nonetheless, Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that
17 it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. Since
18 2012, Plaintiff is informed and believes that detailers for Endo have informed California doctors,
19 including doctors in Alameda County, that Opana ER is harder to abuse and given demonstrations
20 to nurse practitioners about Opana ER’s purported abuse deterrent properties.

21 157. In its 2016 settlement with the NY AG, Endo agreed to no longer make statements
22 in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found those
23

24 ⁴³ Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public
25 Integrity (Dec. 15, 2016), available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-
push-profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed December 20, 2017).

26 ⁴⁴ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a
27 serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be
28 withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that
Endo withdraw Opana ER from the market. Press Release, “FDA requests removal of Opana ER for risks
related to abuse,” June 8, 2017, available at [https://www.fda.gov/NewsEvents/Newsroom/PressAnnou
ncements/ucm562401.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm) (last accessed December 20, 2017).

1 statements to be false and misleading because there was no difference in the ability to extract the
2 narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge
3 of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy
4 benefit managers.

5 158. Because Orpana ER could be “readily prepared for injection” and was linked to
6 outbreaks of HIV and a serious blood disease, an FDA advisory committee recommended that
7 Opana ER be withdrawn from the market in May 2017. The FDA adopted this recommendation on
8 June 8, 2017, and requested that Endo withdraw Opana ER from the market.

9 159. Likewise, Purdue has engaged and continues to engage in deceptive marketing of
10 its AD opioids—i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not
11 market its opioids based on their abuse deterrent properties. However, Plaintiffs is informed and
12 believes that beginning in 2013 and continuing today, detailers from Purdue regularly uses the so-
13 called abuse deterrent properties of Purdue’s opioid products as a primary selling point to
14 differentiate Purdue’s products from its competitors. Specifically, these detailers: (a) falsely claim
15 that Purdue’s AD opioids prevent tampering and cannot be crushed or snorted; (b) falsely claim
16 that Purdue’s AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to
17 yield a euphoric high, and are disfavored by opioid abusers; (c) falsely claim Purdue’s AD opioids
18 are “safer” than other opioids; and (d) fail to disclose that Purdue’s AD opioids do not impact oral
19 abuse or misuse, and that its abuse deterrent properties can be defeated.

20 160. These statements and omissions by Purdue are false and misleading, and conflict
21 with or are inconsistent with the FDA-approved label for Purdue’s AD opioids, which indicates
22 that (a) abusers seek them because of their high “likability” when snorted, (b) their abuse deterrent
23 properties can be defeated, and (c) they can be abused orally notwithstanding their abuse deterrent
24 properties. Notably, the FDA-approved label for Purdue’s AD opioids does *not* indicate that AD
25 opioids prevent or reduce abuse, misuse, or diversion.

26 161. Purdue knew and should have known that reformulated OxyContin is not better at
27 tamper resistance than the original OxyContin and is still regularly tampered with and abused. A
28 2015 study also shows that many opioid addicts are abusing Purdue’s AD opioids through oral

1 intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study
 2 defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug.
 3 And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted
 4 to other drugs such as heroin.⁴⁵ Despite this, J. David Haddox—the Vice President of Health Policy
 5 for Purdue—falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
 6 being abused in large numbers.⁴⁶

7 162. Testimony in litigation against Purdue and other evidence indicates that Purdue
 8 knew and should have known that “reformulated OxyContin is not better at tamper resistance than
 9 the original OxyContin” and is still regularly tampered with and abused. Websites and message
 10 boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper
 11 with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking
 12 soda or fruit juice in which the tablet has been dissolved. Even Purdue's own website describes a
 13 study it conducted that found continued abuse of OxyContin with so-called abuse deterrent
 14 properties. Finally, there are no studies indicating that Purdue's AD opioids are safer than any other
 15 opioid products.

16 163. The development, marketing, and sale of AD opioids is a continuation of the
 17 Manufacturer Defendants' strategy of using misinformation to drive profit. The Manufacturer
 18 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused
 19 by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more
 20 expensive than other opioid products even though they provide little or no additional benefit in the
 21 prevention of opioid abuse.

22 164. These false and misleading claims about the abuse deterrent properties of their
 23 opioids are especially troubling. First, Manufacturer Defendants are using these claims in a spurious
 24 attempt to rehabilitate their image as responsible opioid manufacturers. Plaintiff is informed and
 25

26 ⁴⁵ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid
 abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-
 430.

27 ⁴⁶ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose*
 28 *epidemic*, Business Insider (Mar. 14, 2016), available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed December 20, 2017).

believes that Purdue has conveyed to prescribers that its sale of AD opioids is “atonement” for its earlier sins (even though its true motive was to preserve the profits it otherwise would have lost when its patent for OxyContin expired). Indeed, Purdue introduced its first AD opioid days before its patent for its non-AD opioid would have expired. Purdue even petitioned the FDA to withdraw its non-AD opioid as unsafe as a way to prevent generic competition. Second, these claims are falsely assuaging doctors’ concerns about the toll caused by the explosion in opioid prescriptions and use, and encouraging doctors to prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are not. Finally, these claims are causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit in the prevention of opioid abuse.

165. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

D. The Manufacturer Defendants Misrepresented the Benefits of Chronic Opioid Therapy

166. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was significant upside to long-term opioid use.

167. The 2016 CDC Guideline makes clear, there is “*insufficient evidence* to determine long-term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found that “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.

168. In 2013, the FDA also stated that it was “not aware of adequate and well-controlled studies of opioids use longer than 12 weeks.”

169. Despite this, the Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use, and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have the Manufacturer Defendants failed to correct these

1 false and misleading claims, but they have continued to make them today.

2 170. For example, the Manufacturer Defendants falsely claimed that long-term opioid
3 use improved patients' function and quality of life. Some illustrative examples of these deceptive
4 claims that were made by, and are continuing to be made by Defendants are described below:

- 5 a. On information and belief, Actavis distributed an advertisement that claimed
6 that the use of Kadian to treat chronic pain would allow patients to return to
7 work, relieve "stress on your body and your mental health," and help patients
8 enjoy their lives.
- 9 b. Endo distributed advertisements that claimed that the use of Opana ER for
10 chronic pain would allow patients to perform demanding tasks like
11 construction work or work as a chef and portrayed seemingly healthy,
12 unimpaired subjects.
- 13 c. On information and belief, Janssen sponsored and edited a patient education
14 guide entitled *Finding Relief: Pain Management for Older Adults* (2009) –
15 which states as "a fact" that "opioids may make it easier for people to live
16 normally." The guide lists expected functional improvements from opioid use,
17 including sleeping through the night, returning to work, recreation, sex,
18 walking, and climbing stairs and states that "[u]sed properly, opioid
19 medications can make it possible for people with chronic pain to 'return to
20 normal.'"
- 21 d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo
22 and Purdue, taught that relief of pain by opioids, by itself, improved patients'
23 function. The book remains for sale online.
- 24 e. APF's Treatment Options: A Guide for People Living with Pain, sponsored by
25 Cephalon and Purdue, counseled patients that opioids "give [pain patients] a
26 quality of life we deserve." This publication is still available online.
- 27 f. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids,
28 "your level of function should improve; you may find you are now able to
participate in activities of daily living, such as work and hobbies, that you were
not able to enjoy when your pain was worse." Elsewhere, the website touted
improved quality of life (as well as "improved function") as benefits of opioid
therapy. The grant request that Endo approved for this project specifically
indicated NIPC's intent to make misleading claims about function, and Endo
closely tracked visits to the site.
- g. Endo was the sole sponsor, through NIPC, of a series of non-credit educational
programs titled *Persistent Pain in the Older Patient*, which claimed that chronic
opioid therapy has been "shown to reduce pain and improve depressive
symptoms and cognitive functioning." The CME was disseminated via
webcast.
- h. On information and belief, Janssen sponsored, funded, and edited a website,
Let's Talk Pain, in 2009, which featured an interview edited by Janssen
claiming that opioids allowed a patient to "continue to function." This video is
still available today on YouTube.

- i. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 is still available online today.
- j. In a 2015 video on Forbes.com⁴⁷ discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- k. Purdue's, Endo's, Teva's and Janssen's sales representatives have conveyed and continue to convey to prescribers in California, including in Alameda County, the message that opioids will improve patient function.

171. The above claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is ***no good evidence*** that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline, finding:

- a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later"
- b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

172. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

173. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the

⁴⁷ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won't Stop Opioid Overdose Deaths*, Forbes (Apr. 17, 2015), available at <https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed December 20, 2017).

1 FDA warned Actavis that “[w]e are not aware of substantial evidence or substantial clinical
2 experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating
3 pain, taken together with any drug-related side effects patients may experience ... results in any
4 overall positive impact on a patient’s work, physical and mental functioning, daily activities, or
5 enjoyment of life.”⁴⁸ And, in 2008 the FDA sent a warning letter to an opioid manufacturer, making
6 it publicly clear “that [the claim that] patients who are treated with the drug experience an
7 improvement in their overall function, social function, and ability to perform daily activities . . .
8 has not been demonstrated by substantial evidence or substantial clinical experience.”

9 174. The Manufacturer Defendants also falsely and misleadingly emphasized or
10 exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look
11 to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants
12 frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of
13 analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). The Manufacturer
14 Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from
15 opioids.⁴⁹ The Manufacturer Defendants have overstated the number of deaths from NSAIDs and
16 have prominently featured the risks of NSAIDs, while minimizing or failing to mention the serious
17 risks of opioids. Once again, these misrepresentations by the Manufacturer Defendants contravene
18 pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed,
19 the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids
20 should only be used as a last resort “in patients for which alternative treatment options” like non-
21 opioid drugs “are inadequate.” And the 2016 CDC Guideline states that NSAIDs, not opioids,
22 should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

23 175. In addition, Purdue has misleadingly promoted OxyContin as being unique among
24

25 ⁴⁸ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Comm’n’s, to Doug Boothe,
26 CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at [http://wayback.archive-
it.org/7993/20170112063027/http://www.fda.gov/Drugs/
GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofVi
olationLetterstoPharmaceuticalCompanies/ucm259240.htm](http://wayback.archive-it.org/7993/20170112063027/http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm) (last accessed December 20, 2017).

27 ⁴⁹ See, e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing
28 massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids), available at
http://www.painmedicineneeds.com/download/BtoB_Opana_WM.pdf (last accessed December 19, 2017).

1 opioids in providing 12 continuous hours of pain relief with one dose. Plaintiff is informed and
 2 believes that Purdue's detailers have told prescribers in California within the last two years that
 3 OxyContin lasts 12 hours. In fact, OxyContin does not last for 12 hours, which is an indisputable
 4 fact that Purdue has known at all times relevant to this action. Upon information and belief,
 5 Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients
 6 and in under 10 hours in more than half. This is because OxyContin tablets release approximately
 7 40% of their active medicine immediately, after which release tapers. This triggers a powerful
 8 initial response, but provides little or no pain relief at the end of the dosing period, when less
 9 medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in
 10 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This
 11 not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes
 12 OxyContin more dangerous because the declining pain relief patients experience toward the end of
 13 each dosing period drives them to take more OxyContin before the next dosing period begins,
 14 quickly increasing the amount of drug they are taking and spurring growing dependence.

15 176. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even
 16 though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant
 17 individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is
 18 approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly
 19 prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve
 20 Fentora for the treatment of chronic pain because of the potential harm.

21 177. Despite this, Plaintiff is informed and believes that Cephalon conducted and
 22 continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and
 23 other non-cancer conditions for which it was not approved, appropriate, or safe.⁵⁰ As part of this
 24 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by
 25 its sales representatives to give doctors the false impression that Actiq and Fentora are safe and
 26

27 ⁵⁰ See Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million*
 28 *& Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), available at
<https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed December 21,
 2017).

1 effective for treating non-cancer, chronic pain.

2 178. Cephalon's deceptive marketing gave doctors and patients the false impression that
3 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved
4 by the FDA for such uses. For example:

- 5 a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of
6 Persistent and Breakthrough Pain, published in a supplement of Pain Medicine
7 News in 2009. The CME instructed doctors that "[c]linically, broad
8 classification of pain syndromes as either cancer- or non-cancer-related has
9 limited utility" and recommended Actiq and Fentora for patients with chronic
10 pain.
- 11 b. Upon information and belief, Cephalon's sales representatives set up hundreds
12 of speaker programs for doctors, including many non-oncologists, which
13 promoted Actiq and Fentora for the treatment of non-cancer pain.
- 14 c. In December 2011, Cephalon widely disseminated a journal supplement
15 entitled "Special Report: An Integrated Risk Evaluation and Mitigation
16 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
17 Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News,
18 and Pain Medicine News – three publications that are sent to thousands of
19 anesthesiologists and other medical professionals. The Special Report openly
20 promotes Fentora for "multiple causes of pain" – and not just cancer pain.

21 179. Purdue's sales representatives have pressed doctors to prescribe its opioids in order
22 to be rewarded with talks paid by Purdue. Plaintiff is informed and believes that Purdue sale
23 representatives have told doctors that in California that they will no longer be asked to give paid
24 talks unless they increase their prescribing of Purdue's drugs.

25 180. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
26 Purdue about its legal "obligation to design and operate a system to disclose ... suspicious orders
27 of controlled substances" and to inform the DEA "of suspicious orders when discovered," Purdue
28 unlawfully failed to report or address illicit and unlawful prescribing of its drugs despite knowing
about it for years. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(e).

181. For over a decade, Purdue has been able to track the distribution and prescribing of
its opioids down to the retail and prescriber levels. Through its extensive network of sales
representatives, Purdue had and continues to have knowledge of the prescribing practices of
thousands of doctors in California and could identify California doctors who displayed red flags
for diversion, including doctors whose waiting rooms were overcrowded, parking lots had

1 numerous out-of-state vehicles, and patients seemed young and healthy, or homeless. Using this
2 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
3 prescribing its drugs.

4 182. Incredibly, rather than report these doctors to state medical boards or law
5 enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue
6 used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that
7 Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and
8 sale of generic copies of the drug because the drug was too likely to be abused. In an interview with
9 the Los Angeles Times, Purdue’s senior compliance officer acknowledged that in five years of
10 investigating suspicious pharmacies, Purdue failed to take action, including in circumstances where
11 Purdue employees personally witnessed the diversion of its drugs. Purdue also failed to take action
12 with prescribers. Despite its knowledge of illegal prescribing, Purdue did not report until years after
13 law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin
14 tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing
15 so, Purdue protected its own profits at the expense of public health and safety.

16 183. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
17 Purdue’s sales representatives failed to timely report suspicious prescribing and continued to detail
18 those prescribers even after they were placed on a “no-call” list.

19 184. As Dr. Mitchell Katz, director of the Los Angeles County Department of Health
20 Services, said in a Los Angeles Times article, “Any drug company that has information about
21 physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s
22 lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the
23 company for failing to adequately address suspicious prescribing. Yet, on information and belief,
24 Purdue continues to profit from the prescriptions by such prolific prescribers.

25 185. Like Purdue, Endo has been cited for its failure to set up an effective system for
26 identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the NY
27 AG found that Endo: (a) failed to require sales representatives to report signs of abuse, diversion,
28 and inappropriate prescribing; (b) paid bonuses to sales representatives for detailing prescribers

1 who were subsequently arrested or convicted for illegal prescribing; and (c) failed to prevent sales
2 representatives from visiting prescribers whose suspicious conduct had caused them to be placed
3 on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives
4 detailed prescribers who were convicted of illegal prescribing of opioids, those representatives
5 could have recognized potential signs of diversion and reported those prescribers but failed to do
6 so.

7 186. The Manufacturer Defendants made, promoted, and profited from their
8 misrepresentations about the risks and benefits of opioids for chronic pain even though they knew
9 that their misrepresentations were false and misleading. The history of opioids, as well as research
10 and clinical experience over the last 20 years, established that opioids were highly addictive and
11 responsible for a long list of very serious adverse outcomes. The Manufacturer Defendants had
12 access to scientific studies, detailed prescription data, and reports of adverse events, including
13 reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term
14 opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.
15 More recently, the FDA and CDC have issued pronouncements based on the medical evidence that
16 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations, and
17 Endo and Purdue have recently entered into agreements prohibiting them from making some of the
18 same misrepresentations described in this Complaint.

19 187. On information and belief, the Manufacturer Defendants coordinated their
20 messaging through national and regional sales and speaker trainings and coordinated
21 advertisements and marketing materials.

22 188. Moreover, at all times relevant to this Complaint, the Manufacturer Defendants took
23 steps to avoid detection of and to fraudulently conceal their deceptive marketing. For example, the
24 Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid
25 therapy by funding and working through third parties like Front Groups and KOLs. The
26 Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and
27 organizations, and relied on them to vouch for the accuracy and integrity of the Manufacturer
28 Defendants' false and misleading statements about the risks and benefits of long-term opioid use

1 for chronic pain.

2 189. Manufacturer Defendants also never disclosed their role in shaping, editing, and
3 approving the content of information and materials disseminated by these third parties.
4 Manufacturer Defendants exerted considerable influence on these promotional and “educational”
5 materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations
6 companies that were not, and have not yet become, public. For example, painknowledge.org, which
7 is run by the NIPC, did not disclose Endo’s involvement. Other Manufacturer Defendants, such as
8 Purdue and Janssen, ran similar websites that masked their own direct role.

9 190. Finally, the Manufacturer Defendants manipulated their promotional materials and
10 the scientific literature to make it appear that the information and materials disseminated by third
11 parties were accurate, truthful, and supported by objective evidence when they were not. The
12 Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as
13 evidence for propositions the studies did not support. The lack of support for the Manufacturer
14 Defendants’ deceptive messages was not apparent to medical professionals who relied upon them
15 in making treatment decisions, nor could it have been detected by Alameda County.

16 191. The Manufacturer Defendants’ efforts to artificially increase the number of opioid
17 prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016
18 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and
19 has increased in parallel with [opioid] overdoses.”⁵¹ Many abusers start with legitimate
20 prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids
21 for chronic pain are critical “[t]o reverse the epidemic of opioid drug overdose deaths and prevent
22 opioid-related morbidity.”⁵² Accordingly, the Manufacturer Defendants’ false and misleading
23 statements directly caused the current opioid epidemic. The Manufacturer Defendants’
24 misrepresentations deceived and continue to deceive doctors and patients in California, including
25 in Alameda County, about the risks and benefits of long-term opioid use. California doctors confirm

26
27 ⁵¹ Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*,
Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at
28 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm> (last accessed December 20, 2017).

⁵² *Id.*

1 this. Studies also reveal that many doctors and patients are not aware of or do not understand these
2 risks and benefits. Indeed, patients often report that they were not warned they might become
3 addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than
4 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.
5 Plaintiff is informed and believes that California residents were never told that they might become
6 addicted to opioids when they started taking them, were told that they could easily stop using
7 opioids, or were told that the opioids they were prescribed were less addictive than other opioids.

8 192. Numerous doctors and substance abuse counselors in California note that many of
9 their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
10 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
11 centers in California report that they treat a significant percentage – i.e., as high as 80% – of patients
12 for opioid addiction.

13 193. The Manufacturer Defendants knew and should have known that their
14 misrepresentations about the risks and benefits of long-term opioid use were false and misleading
15 when they made them.

16 194. The Manufacturer Defendants' deceptive marketing of the abuse-deterrent
17 properties of their opioids caused and continue to cause doctors in California, including doctors in
18 Alameda County, to prescribe opioids for chronic pain conditions such as back pain, headaches,
19 arthritis, and fibromyalgia, rather than prescribing less addictive medications. Absent
20 Manufacturers Defendants' deceptive marketing scheme, these doctors would not have prescribed
21 as many opioids to as many patients, and there would not have been as many opioids available for
22 misuse and abuse or as much demand for those opioids.

23 195. Manufacturer Defendants' deceptive marketing of the abuse-deterrent properties of
24 their opioids have caused and continue to cause the prescribing and use of opioids to explode in
25 California, including in Alameda County. Opioids are the most common means of treatment for
26 chronic pain; 20% of office visits now include the prescription of an opioid, and 4 million
27 Americans per year are prescribed a long-acting opioid.

28 196. In California, including Alameda County, Manufacturer Defendants' deceptive

1 marketing of the abuse-deterrent properties of their opioids during the past few years has been
 2 particularly effective. For example, one survey reports that pain specialists were more likely to
 3 recognize that OxyContin had abuse deterrent properties and to prescribe OxyContin specifically
 4 because of those properties. Further, prescribers who knew of OxyContin's abuse deterrent
 5 properties were using more of it than those who did not know it was an AD opioid. Although sales
 6 of AD opioids still represent only a small fraction of opioids sold (less than 5% of all opioids sold
 7 in 2015), they represent a disproportionate share of opioid sales revenue (\$2.4 billion or
 8 approximately 25% in opioid sales revenue in 2015).

9 197. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
 10 increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer
 11 Defendants' spending on opioid marketing totaled approximately \$91 million in 2000. By 2011,
 12 that spending had tripled to \$288 million.

13 **E. All Defendants Created an Illicit Market for Opioids**

14 198. In addition to the allegations above, all Defendants played a role in the creation of
 15 an illicit market for prescription opioids, further fueling the opioid epidemic.

16 199. Defendants' distribution of opioids was driven by national policies, coordination,
 17 plans, and procedures that were the same in California as they were across the rest of the United
 18 States. Defendants worked together in an illicit enterprise, engaging in conduct that was not only
 19 illegal, but in certain respects anti-competitive, with the common purpose and achievement of
 20 vastly increasing their respective profits and revenues by exponentially expanding a market that the
 21 law intended to restrict. At all relevant times, Defendants were in possession of national, regional,
 22 state, and local prescriber- and patient-level data that allowed them to track prescribing patterns
 23 over time. Defendants utilized this data to further their distribution scheme and to ensure the largest
 24 possible financial return.

25 200. Each participant in the supply chain shares the responsibility for controlling the
 26 availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of
 27 prescription opioids is broken, allowing drugs to be transferred from a legitimate channel of
 28 distribution or use to an illegitimate channel of distribution or use.

1 201. Diversion can occur at any point in the opioid supply chain.

2 202. For example, diversion can occur at the wholesale level of distribution when
3 distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders
4 of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large
5 size, orders that are disproportionately large in comparison to the population of a community served
6 by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

7 203. Diversion can occur at pharmacies or retailers when a pharmacist fills a prescription
8 despite having reason to believe it was not issued for a legitimate medical purpose or not in the
9 usual course of practice. Some of the signs that a prescription may have been issued for an
10 illegitimate medical purpose include when the patient seeks to fill multiple prescriptions from
11 different doctors (known as doctor shopping), when they travel great distances between the doctor
12 or their residence and the pharmacy to get the prescription filled, when they present multiple
13 prescriptions for the largest dose of more than one controlled substance, or when there are other
14 “red flags” surrounding the transaction. These red flags should trigger closer scrutiny of the
15 prescriptions by the pharmacy and lead to a decision that the patient is not seeking the medication
16 to treat a legitimate medical condition.

17 204. Diversion occurs through the use of stolen or forged prescriptions or the sale of
18 opioids without prescriptions, including patients seeking prescription opioids under false pretenses.
19 Opioids can also be diverted when stolen by employees or others.

20 205. Opioid diversion occurs at an alarming rate in the United States.

21 206. Each participant in the supply chain, including each Defendant, has a common law
22 duty to prevent diversion by using reasonable care under the circumstances. This includes a duty
23 not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative
24 conduct and thereafter realizes or should realize that such conduct has created an unreasonable risk
25 of harm to another is under a duty to exercise reasonable care to prevent the threatened harm.

26 207. Defendants, and not Plaintiff, controlled the manufacture, marketing, and
27 distribution of prescription opioids within Plaintiff’s boundaries. As such, Defendants were in the
28 best position to protect Plaintiff and the public from the risk of harm of misuse of these products.

1 Defendants owed Plaintiff a common law duty of care in light of that foreseeable risk.

2 208. Manufacturer Defendants owed Plaintiff a duty to exercise reasonable care in the
3 promotion of prescription opioids in and around Plaintiff's boundaries. Defendants breached that
4 duty in their misleading and inaccurate promotion of prescription opioids.

5 209. Distributor Defendants owed Plaintiff a duty to exercise reasonable care in the sale
6 and distribution of opioids in and around Plaintiff's boundaries. Defendants breached that duty in
7 their failure to prevent diversion of prescription opioids and in their refusal to report and halt
8 suspicious orders.

9 **210.** In addition to their common law duties, Defendants possess duties under California
10 law to develop and maintain a system to track suspicious orders of prescription opioids. Both
11 Manufacturer and Distributor Defendants are subject to the reporting requirements of 16 CCR §
12 1782, and Distributor Defendants are further subject to California Business & Professions Code §§
13 4164 and 4169.1.

14 211. Separately, Defendants also are subject to federal statutory requirements of the
15 Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"), and its implementing regulations.
16 Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled
17 substances] out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444, 1970
18 U.S.C.C.A.N. 4566, 4572.

19 212. Defendants' repeated and prolific violations of these requirements show that they
20 have failed to meet the relevant standard of conduct that society expects of them: the duty to
21 exercise reasonable care in the promotion of prescription opioids. In doing so, they acted with
22 willful disregard for Alameda County and the people therein.

23 213. California law requires Defendants to report suspicious orders of dangerous drugs
24 subject to abuse, and to develop and maintain systems to detect and report such activity. This
25 framework acts as a system of checks and balances from the manufacturing level through delivery
26 of the controlled substance to the patient or ultimate user.

27 214. Thus, all opioid distributors are required to maintain effective controls against
28 opioid diversion. They are required to create and use a system to identify and report to the California

1 State Board of Pharmacy downstream suspicious orders of controlled substances, such as orders of
2 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
3 and/or orders of unusual frequency. To comply with these requirements, distributors must know
4 their customers, must conduct due diligence, must report suspicious orders, and must terminate
5 orders if there are indications of diversion.

6 215. Moreover, every person or entity that manufactures, distributes, or dispenses opioids
7 must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill
8 their obligations under the CSA.

9 216. Under the CSA, anyone authorized to handle controlled substances must track
10 shipments. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an
11 automated drug reporting system that records and monitors the flow of Schedule II controlled
12 substances from the point of manufacture through distribution to the point of sale. ARCOS
13 accumulates data on distributors' controlled substances and transactions, which are then used to
14 identify diversion. Each person or entity registered to distribute ARCOS reportable controlled
15 substances, including opioids, must report each acquisition and distribution transaction to the DEA.
16 *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each registrant must also maintain a complete, accurate,
17 and current record of each substance manufactured, imported, received, sold, delivered, exported,
18 or otherwise disposed of.

19 217. Plaintiff does not bring causes of action based on violations of federal statutes and
20 regulations. However, the existence of these complicated regulatory schemes shows Defendants'
21 intimate knowledge of the dangers of diversion of prescription opioids and the existence of a
22 thriving illicit market for these drugs. Defendants breached their duties to Plaintiff despite this
23 knowledge and longstanding regulatory guidance of how to deter and prevent diversion of
24 prescription opioids.

25 **1. The Distributor Defendants Negligently Failed to Control the Flow of**
26 **Opioids to Alameda County Through Illicit Channels**

27 218. The Distributor Defendants have been and continue to be well-aware of problems
28 posed by their failure to combat diversion of opioids. For example, the DEA has provided guidance

1 to distributors on how to combat opioid diversion, and Plaintiff is informed and believes that the
2 DEA has conducted one-on-one briefings with distributors regarding downstream customer sales,
3 due diligence, and regulatory responsibilities since 2006. Plaintiff is further informed and believes
4 that the DEA also provides distributors with data on controlled substance distribution patterns and
5 trends, including data on the volume and frequency of orders and the percentage of controlled
6 versus non-controlled purchases. The distributors are also given case studies, legal findings against
7 other registrants, and ARCOS profiles of their customers whose previous purchases may have
8 reflected suspicious ordering patterns. The DEA even pointed out “red flags” that the Distributor
9 Defendants should look for in order to identify potential diversion.

10 219. Since 2007, the DEA has hosted at least five conferences to provide registrants with
11 updated information about diversion trends and regulatory changes that affect the drug supply
12 chain, the distributor initiative, and suspicious order reporting. All of the major distributors,
13 including McKesson, AmerisourceBergen, and Cardinal attended at least one of these conferences.
14 The conferences allowed the registrants to ask questions and raise concerns. These registrants could
15 also request clarification on DEA policies, procedures, and interpretations of the CSA and
16 implementing regulations.

17 220. Since 2008, the DEA also has participated in numerous meetings and events with
18 the legacy Healthcare Distribution Management Association (HDMA), now known as the
19 Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and
20 distributors like McKesson, AmerisourceBergen, and Cardinal. DEA representatives have provided
21 guidance to the association concerning suspicious order monitoring, and the association has
22 published guidance documents for its members on suspicious order monitoring, reporting
23 requirements, and the diversion of controlled substances. (HDMA, “Industry Compliance
24 Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,”
25 (2008).)

26 221. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion
27 Control sent letters to all registered distributors providing guidance on suspicious order monitoring
28 and the responsibilities and obligations of registrants to prevent diversion.

222. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The December 2007 letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

223. Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

224. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibility to prevent diversion. They have made statements assuring the public they supposedly are undertaking a duty to curb the opioid epidemic.

225. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

226. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

227. On their face, these assurances that they would identify and eliminate criminal activity and curb the opioid epidemic, create a duty for the Distributor Defendants to take reasonable measures to do just that.

228. Despite their duties to prevent diversion, the Distributor Defendants have knowingly

1 or negligently allowed diversion.⁵³

2 229. Their misconduct and negligent failure to prevent diversion is demonstrated by the
3 fact that the DEA has been repeatedly forced to take action to force compliance, including (a) 178
4 registrant actions between 2008 and 2012, (b) 76 orders to show cause issued by the Office of
5 Administrative Law Judges, and (c) 41 actions involving immediate suspension orders.⁵⁴ The
6 Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and
7 other penalties, including:

- 8 a. In a 2017 Administrative Memorandum of Agreement between McKesson and
9 the DEA, McKesson admitted that it "did not identify or report to [the] DEA
10 certain orders placed by certain pharmacies which should have been detected
11 by McKesson as suspicious based on the guidance contained in the DEA
12 Letters." McKesson was fined \$150,000,000;⁵⁵
- 13 b. McKesson has a history of repeatedly failing to perform its duties. In May
14 2008, McKesson entered into a settlement with the DEA on claims that
15 McKesson failed to maintain effective controls against diversion of controlled
16 substances. McKesson allegedly failed to report suspicious orders from rogue
17 Internet pharmacies around the country, resulting in millions of doses of
18 controlled substances being diverted. McKesson's system for detecting
19 "suspicious orders" from pharmacies was so ineffective and dysfunctional that
20 at one of its facilities in Colorado between 2008 and 2013, it filled more than
21 1.6 million orders, for tens of millions of controlled substances, but it reported
22 just 16 orders as suspicious, all from a single consumer;
- 23 c. On November 28, 2007, the DEA issued an Order to Show Cause and
24 Immediate Suspension Order against a Cardinal Health facility in Auburn,
25 Washington, for failure to maintain effective controls against diversion;
- 26 d. On December 5, 2007, the DEA issued an Order to Show Cause and
27 Immediate Suspension Order against a Cardinal Health facility in Lakeland,
28 Florida, for failure to maintain effective controls against diversion;

⁵³ Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post (Oct. 15, 2017), available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

⁵⁴ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at <https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed January 8, 2018).

⁵⁵ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download> (last accessed December 21, 2017).

- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion;
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion;
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States;⁵⁶
- h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion;
- i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states;
- j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act;⁵⁷
- k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year;
- l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies; and
- m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels.

230. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

231. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid

⁵⁶ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, Wash. Post (Jan. 11, 2017), available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

⁵⁷ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed December 21, 2017).

1 diversion created an enormous black market for prescription opioids, which market extended to
2 Alameda County and its residents. Each Distributor Defendant knew or should have known that the
3 opioids reaching Alameda County were not being consumed for medical purposes and that the
4 amount of opioids flowing to Alameda County was far in excess of what could be consumed for
5 medically necessary purposes.

6 232. The Distributor Defendants negligently or intentionally failed to adequately control
7 their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled
8 substances would have anticipated the danger of opioid diversion and protected against it by, for
9 example: (a) taking greater care in hiring, training, and supervising employees; (b) providing
10 greater oversight, security, and control of supply channels; (c) looking more closely at the
11 pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in
12 amounts greater than the populations in those areas would warrant; (d) investigating demographic
13 or epidemiological facts concerning the increasing demand for narcotic painkillers in and around
14 Alameda County; (e) providing information to pharmacies and retailers about opioid diversion; and
15 (f) in general, simply following applicable statutes, regulations, professional standards, and
16 guidance from government agencies and using a little bit of common sense.

17 233. On information and belief, the Distributor Defendants made little to no effort to visit
18 the pharmacies servicing the areas around Alameda County to perform due diligence inspections
19 to ensure that the controlled substances the Distributor Defendants had furnished were not being
20 diverted to illegal uses.

21 234. On information and belief, the compensation the Distributor Defendants provided
22 to certain of their employees was affected, in part, by the volume of their sales of opioids to
23 pharmacies and other facilities servicing the areas around Alameda County, thus improperly
24 creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic
25 of opioid abuse.

26 235. It was reasonably foreseeable to the Distributor Defendants that their conduct in
27 flooding the market in and around Alameda County with highly addictive opioids would allow
28 opioids to fall into the hands of children, addicts, criminals, and other unintended users.

1 236. It was reasonably foreseeable to the Distributor Defendants that, when unintended
2 users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses,
3 and death. It was also reasonably foreseeable that many of these injuries would be suffered by
4 Alameda County residents, and that the costs of these injuries would be borne by Alameda County.

5 237. The Distributor Defendants knew or should have known that the opioids being
6 diverted from their supply chains would contribute to the opioid epidemic faced by Alameda
7 County, and would create access to opioids by unauthorized users, which, in turn, perpetuates the
8 cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

9 238. The Distributor Defendants were aware of widespread prescription opioid abuse in
10 and around Alameda County, but, on information and belief, they nevertheless persisted in a pattern
11 of distributing commonly abused and diverted opioids in geographic areas, in such quantities, and
12 with such frequency that they knew or should have known these commonly abused controlled
13 substances were not being prescribed and consumed for legitimate medical purposes.

14 239. The use of opioids by Alameda County residents who were addicted or who did not
15 have a medically necessary purpose could not have occurred without the knowing cooperation,
16 assistance, or negligent failure to act of and by the Distributor Defendants. If the Distributor
17 Defendants adhered to effective controls to guard against diversion, Alameda County and its
18 residents would have avoided significant injury.

19 240. The Distributor Defendants made substantial profits over the years based on the
20 diversion of opioids into Alameda County. The Distributor Defendants knew that Alameda County
21 would be unjustly forced to bear the costs of these injuries and damages.

22 241. The Distributor Defendants' intentional distribution of excessive amounts of
23 prescription opioids showed an intentional or reckless disregard for the safety of Alameda County
24 and its residents. Their conduct poses a continuing threat to the health, safety, and welfare of
25 Alameda County.

26 242. The state laws at issue here are public safety laws.

27 243. The Distributor Defendants' violations constitute prima facie evidence of
28 negligence under state law.

2. The Manufacturer Defendants Negligently Failed to Control the Flow of Opioids to Alameda County Through Illicit Channels

244. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under California law.

245. In addition to a common law duty to exercise reasonable care in the promotion and marketing of opioids, the Manufacturer Defendants also are required to report all sales of dangerous drugs subject to abuse as designated by the California Board of Pharmacy in excess of amounts determined by the Board. *See* 16 CCR 1782.

246. On information and belief, for over a decade the Manufacturer Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Manufacturer Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Manufacturer Defendants breached their duties under state law.

247. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

248. The Manufacturer Defendants’ actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful

1 diversion of opioids into Alameda County.

2 **F. The Defendants Knowingly Profit from an Interstate Opioid Crisis**

3 249. As the demand for prescription opioids grew, fueled by their potency and purity,
4 interstate commerce flourished: opioids moved from areas of high supply to areas of high demand,
5 traveling across state, city, and county lines in a variety of ways.

6 250. First, prescriptions written in one state would, under some circumstances, be filled
7 in a different state. But even more significantly, individuals transported opioids from one
8 jurisdiction specifically to sell them in another.

9 251. When authorities in one state cracked down on opioid suppliers, out-of-state
10 suppliers filled the gaps. Florida in particular assumed a prominent role because its lack of
11 regulatory oversight created a fertile ground for pill mills. Residents of many states would simply
12 drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The
13 practice became so common that authorities dubbed these individuals “prescription tourists.”

14 252. The facts surrounding numerous criminal prosecutions illustrate this common
15 practice. For example, in May 2018 a mother son crime duo based out of New Jersey was caught
16 flying to California in attempts to obtain additional sources of supply for their drug operation which
17 consisted of trafficking counterfeit prescription pills, other opiates, cocaine and marijuana.⁵⁸

18 253. In another example, a man from Warren County, Ohio, who was sentenced to four
19 years for transporting prescription opioids from Florida to Ohio, explained that he could get a
20 prescription for 180 pills from a quick appointment in West Palm Beach, and then sell them back
21 home in Ohio for as much as \$100 a pill—ten times the pharmacy price.⁵⁹ In Columbus, Ohio, a
22 DEA investigation led to the 2011 prosecution of sixteen individuals involved in the “oxycodone
23 pipeline between Ohio and Florida.”⁶⁰ When officers searched the Ohio home of the alleged leader

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25 ⁵⁸ *United States of America v. Candace Gottlieb*, Case No. 18-1015 (AMD), (D.N.J. May 30, 2018).

26 ⁵⁹ Andrew Welsh-Huggins, Associated Press, ‘*Prescription Tourists’ Thwart States’ Crackdown on Illegal Sale of Painkillers*, NBC News, available at http://www.nbcnews.com/id/48111639/ns/us_news-crime_and_courts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2Wy71 (last updated July 8, 2012, 12:28 PM).

27 ⁶⁰ *16 Charged in ‘Pill Mill’ Pipeline*, Columbus Dispatch (June 7, 2011), available at
28 <http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html> (last accessed July 25, 2018).

1 of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone,
2 and \$80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying
3 couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of
4 U.S. District Judge Michael Watson, contributing to a “pipeline of death.”⁶¹

5 254. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill
6 mill; the U.S. attorney’s office found that most of the pain clinic’s customers came from other
7 states.⁶² Another investigation in Atlanta led to the 2017 conviction of two pharmacists who
8 dispensed opioids to customers of a pill mill across from the pharmacy. Again, many of those
9 customers were from other states.⁶³

10 255. In yet another case, defendants who operated a pill mill in south Florida within
11 Broward County were tried in eastern Kentucky based on evidence that large numbers of customers
12 transported oxycodone back to the area for both use and distribution by local drug trafficking
13 organizations. As explained by the Sixth Circuit in its decision upholding the venue decision,
14 “[d]uring its existence, the clinic generated over \$10 million in profits. To earn this sum required
15 more business than the local market alone could provide. Indeed, only about half of the [Pain Center
16 of Broward]’s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-
17 of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft.
18 Lauderdale, including from Ohio, Georgia, and Massachusetts.”⁶⁴ The court further noted that the
19 pill mill “gained massive financial benefits by taking advantage of the demand for oxycodone by
20 Kentucky residents.”⁶⁵

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22 ⁶¹ Associated Press, *Leader of Ohio Pill-Mill Trafficking Scheme Sentenced*, Star Beacon (July 16, 2015),
23 available at http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html (last accessed July 25, 2018).

24 ⁶² Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Four Defendants Plead Guilty to Operating a “Pill Mill” in Lilburn, Georgia* (May 14, 2015), available at
25 <https://www.justice.gov/usao-ndga/pr/four-defendants-plead-guilty-operating-pill-mill-lilburn-georgia> (last accessed July 25, 2018).

26 ⁶³ Press Release, U.S. Dep’t of Just., U.S. Atty’s Off., Northern District of Ga., *Two Pharmacists Convicted for Illegally Dispensing to Patients of a Pill Mill* (Mar. 29, 2017), available at
27 <https://gdna.georgia.gov/press-releases/2017-03-30/two-pharmacists-convicted-illegally-dispensing-patients-pill-mill> (last accessed July 25, 2018).

28 ⁶⁴ *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

⁶⁵ *Id.* at 861.

256. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt.⁶⁶ Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag.⁶⁷ If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over.⁶⁸ Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the “Oxy Express.”⁶⁹

257. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.⁷⁰

258. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California.⁷¹ And, according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.

259. Along the west coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington.⁷²

⁶⁶ John Temple, *American Pain, How a Young Felon and His Ring of Doctors Unleashed America's Deadliest Drug Epidemic* 171 (2016).

⁶⁷ *Id.* at 172

⁶⁸ *Id.* at 171

⁶⁹ *Id.*

⁷⁰ Andrew Welsh-Huggins, Associated Press, ‘Prescription Tourists’ Thwart States’ Crackdown on Illegal Sale of Painkillers, NBC News, available at <http://www.nbcnews.com/id/48111639/ns/usnews-crimeandcourts/t/prescription-tourists-thwart-states-crackdown-illegal-sale-painkillers/#.WtdyKE2WY71> (last accessed July 25, 2018).

⁷¹ Nok-Noi Ricker, *Slaying of Florida firefighter in Maine Puts Focus on Interstate 95 Drug Running*, Bangor Daily News (March 9, 2012), available at <http://bangordailynews.com/2012/03/09/news/state/slaying-of-florida-firefighter-in-maine-puts-focus-on-interstate-95-drug-running> (last accessed July 25, 2018)

⁷² Harriet Ryan et al., *How Black-Market OxyContin Spurred a Town’s Descent into Crime, Addiction and*

1 Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle.⁷³ The
 2 Everett-based dealer who received the pills from southern California wore a diamond necklace in
 3 the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram
 4 OxyContin—connecting Los Angeles and Washington state.

5 260. Defendants certainly were aware, or should have been aware, that pill mills from
 6 around the country were pushing its products. Defendants purchased nationwide, regional, state,
 7 and local prescriber- and patient-level data from data vendors that allowed them to track prescribing
 8 trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills,
 9 etc. The data vendors' information purchased by the Defendants allowed them to view, analyze,
 10 compute, and track their competitors' sales, and to compare and analyze market share information.

11 261. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies
 12 that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants
 13 with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory,
 14 regarding competing drugs, and analyzed the market share of those drugs.

15 262. Not only were Defendants aware of the pill mills, but Defendants' sales incentives
 16 rewarded sales representatives who happened to have pill mills within their territories, enticing
 17 those representatives to look the other way even when their in-person visits to such clinics should
 18 have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting
 19 massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away
 20 to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed
 21 criminal charges against the doctors. But Purdue's sales representative for that territory, Eric
 22 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local
 23 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,
 24 Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,
 25 Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication
 26

27 _____
 28 Heartbreak, Los Angeles Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/> (last accessed July 25, 2018)

⁷³ *Id.*

1 inappropriately, such activity would continue regardless of whether we contacted the doctor or not.

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3 263. In another example, a Purdue sales manager informed her supervisors in 2009 about
4 a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her
5 sales representative “it was packed with a line out the door, with people who looked like gang
6 members,” and that she felt “very certain that this an organized drug ring[.]”⁷⁵ She wrote, “This is
7 clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue
8 responded that while they were “considering all angles,” it was “really up to [the wholesaler] to
9 make the report.”⁷⁶ This pill mill was the source of 1.1 million pills trafficked to Everett,
10 Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in
11 2010 to inform the authorities.

12 264. Abundant evidence, thus, establishes that prescription opioids migrated between
13 states, counties, and cities and that Defendants were aware of it. As a result, Defendants’ public
14 nuisance is not limited to the local or state level, but is national in scope. Additionally, prescription
15 data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and
16 diversion problem in that specific area. As the criminal prosecutions referenced above show, if
17 prescription opioid pills were hard to get in one area, they migrated from another. The
18 manufacturers and distributors were fully aware of this phenomenon and profited from it.

19 265. Defendants each knew or should have known that opioid diversion and abuse was
20 occurring on a nationwide scale, and Defendants each profited from disregarding the nationwide
21 illicit prescription opioid trade. In search of even greater profits, the Defendants facilitated and
22 allowed to continue the unlawful diversion of opioids into Alameda County.

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26 ⁷⁴ Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* 204, 289-399
(Rodale 2003).

27 ⁷⁵ Harriet Ryan *et al.*, *More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and*
Addicts. What the Drugmaker Knew, Los Angeles Time (July 10, 2016),
28 <http://www.latimes.com/projects/la-me-oxycontin-part2/>. (last accessed July 30, 2018)

⁷⁶ *Id.*

G. Defendants' Unlawful Conduct and Breaches of Legal Duties Caused the Harm Alleged Herein and Substantial Damages

266. As the Manufacturer Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and the sale of their products, as well as the rates of opioid-related substance abuse, hospitalization, and death among Alameda County residents and across the nation. Meanwhile, the Distributor Defendants have continued to unlawfully ship massive quantities of opioids into communities like Alameda County, fueling the epidemic.

267. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."⁷⁷

268. Opioids are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.⁷⁸

269. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."⁷⁹

270. The increased abuse of prescription opioids—along with growing sales—has contributed to a large number of overdoses and deaths.

271. As shown above, the opioid epidemic has escalated in Alameda County with devastating effects. Substantial opiate-related substance abuse, hospitalization, and death mirror Defendants' increased distribution of opioids.

272. Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, such as heroin, the massive distribution of opioids to Alameda County and areas from which opioids are being diverted to Alameda County, has caused the opioid epidemic to include heroin addiction, abuse, and death.

273. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in Alameda County.

⁷⁷ See Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

⁷⁸ Volkow & McLellan, *supra* note 1.

⁷⁹ Califf, *supra* note 2.

274. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in Alameda County.

275. Defendants repeatedly and purposefully breached their duties under state law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes in Alameda County.

276. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity, and morality in Alameda County. This diversion and the resulting epidemic are direct causes of foreseeable harms incurred by Alameda County and residents of Alameda County.

277. Defendants' intentional and unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Alameda County seeks relief, as alleged herein. Alameda County also seeks the means to abate the epidemic created by the Defendants.

278. Alameda County seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

279. Alameda County seeks economic damages from the Defendants to pay for the costs to permanently eliminate the hazards to public health and safety and abate the public nuisance.

280. Alameda County seeks economic damages from the Defendants to pay for the reduction to tax revenues caused by the epidemic created by the Defendants.

281. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."⁸⁰

282. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the need of patients experiencing pain.⁸¹

283. The community-based problems require community-based solutions that have been

⁸⁰ Rudd, *supra* note 51.

⁸¹ See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al., eds., 2015), available at https://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf (last accessed January 8, 2018).

1 limited by budgetary constraints.

2 284. Having profited enormously through the aggressive sale, misleading promotion, and
3 irresponsible distribution of opioids, Defendants should be required to take responsibility for the
4 financial burdens their conduct has inflicted upon Alameda County.

5 285. The opioid epidemic still rages because the fines and suspensions imposed by the
6 DEA do not change the conduct of the industry. The Defendants pay fines as a cost of doing
7 business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA
8 registration numbers and when one facility is suspended, they simply ship from another facility.

9 286. The Defendants have abandoned their duties imposed by the law, taken advantage
10 of a lack of DEA enforcement, and abused the privilege of distributing controlled substances in
11 Alameda County.

12 287. In the course of conduct described in this Complaint, Defendants have acted with
13 oppression, fraud, and malice, both actual and presumed.

14 **H. The Impact of Opioid Abuse on Alameda County**

15 288. Defendants' creation, through false and misleading advertising and a failure to
16 prevent diversion, of a virtually limitless opioid market has significantly harmed Alameda County
17 and resulted in an abundance of drugs available for non-medical and criminal use and fueled a new
18 wave of addiction and injury. It has been estimated that approximately 60% of the opioids that are
19 abused come, directly or indirectly, through doctors' prescriptions.

20 289. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
21 example, the California Department of Public Health (CDPH) issued a Drug Overdose Health Alert
22 on April 8, 2016 entitled "Fentanyl-Contaminated Street Norco." This alert described the report of
23 48 overdoses and at least 10 deaths over a 10-day period in Sacramento County that appear to be
24 associated with the consumption of a counterfeit version of the prescription drug Norco
25 (acetaminophen and hydrocodone) contaminated with fentanyl. In Los Angeles County, there has
26 been a concerning increase in reported fentanyl-related deaths. While there were on average 40
27 fentanyl-related deaths reported each year from 2011-2013, there were 62 reported deaths in 2014.
28 The Los Angeles County Department of Public Health (LAC DPH) is concerned about a further

1 increase in deaths due to the lethality of fentanyl and reports that it is being found in street drugs
2 and in counterfeit prescription drugs. The deaths in Sacramento County further enhanced this
3 concern.

4 290. Opioid deaths represent the tip of the iceberg. Hospital admissions and emergency
5 room visits have also skyrocketed.⁸² For every opioid overdose death, there are 10 treatment
6 admissions for abuse, 32 emergency room visits, 130 people who are addicted to opioids, and 825
7 nonmedical users of opioids.⁸³ And as reported in May 2016, in California, opioid overdoses
8 resulting in hospital visits increased by 25% (accounting for population growth) from 2011 to 2014.

9 291. Even Alameda County's youngest residents bear the consequences of the opioid
10 abuse epidemic fueled by Defendants' conduct. In 1992, only 2 percent of women admitted for
11 drug treatment services during pregnancy abused opioids. By 2012, opioids were the most
12 commonly abused substance by pregnant women, accounting for 38 percent of all drug treatment
13 admissions.⁸⁴ Many Alameda County women have become addicted to prescription opioids and
14 have used these drugs during their pregnancies. As a result, many Alameda County infants suffer
15 from opioid withdrawal and Neonatal Abstinence Syndrome ("NAS").⁸⁵

16 292. The impact of NAS can be life-long. Most NAS infants are immediately transferred
17 to a neonatal intensive care unit for a period of days, weeks, or even months. NAS can also require
18 an emergency evacuation for care to save the infant's life. Such emergency transportation can cost
19 thousands of dollars for each occurrence.

21 ⁸² Lisa Girion and Karen Kaplan, *Opioids prescribed by doctors led to 92,000 overdoses in ERs in one*
22 *year*, LA Times (Oct. 27, 2014), available at <http://beta.latimes.com/nation/la-sci-sn-opioid-overdose-prescription-hospital-er-20141026-story.html> (last accessed December 21, 2017).

23 ⁸³ Jennifer DuPuis, Associate Dir., Human Servs. Div., Fond du Lac Band of Lake Superior Chippewa,
24 *The Opioid Crisis in Indian Country*, at 37, available at
<https://www.nihb.org/docs/06162016/Opioid%20Crisis%20Part%20in%20Indian%20Country.pdf> (last
25 accessed December 21, 2017); Gery P. Guy, Jr., et al., *Emergency Department Visits Involving Opioid*
Overdoses, US., 2010-2014, Am. J. of Preventive Medicine (Jan. 2018), available at
[http://www.ajpmonline.org/article/S0749-3797\(17\)30494-4/fulltext](http://www.ajpmonline.org/article/S0749-3797(17)30494-4/fulltext) (last accessed December 21, 2017).

26 ⁸⁴ Naana Afua Jumah, *Rural, Pregnant and Opioid Dependent: A Systematic Review*, National Institutes of
27 Health, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915786/> (last accessed December
28 21, 2017).

⁸⁵ Jean Y. Ko et al., *CDC Grand Rounds, Public Health Strategies to Prevent Neonatal Abstinence*
Syndrome, U.S. C.D.C. Morbidity and Mortality Weekly Report, available at
<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6609a2.pdf> (last accessed December 21, 2017).

1 293. Many NAS infants have short-term and long-term developmental issues that prevent
2 them from meeting basic cognitive and motor-skills milestones. Many will suffer from vision and
3 digestive issues; some are unable to attend full days of school. These disabilities follow these
4 children through elementary school and beyond.

5 294. Many of the parents of these children continue to relapse into prescription opioid
6 use and abuse. As a result, many of these children are placed in foster care or adopted.

7 295. Opioid addiction is now the primary reason that Californians seek substance abuse
8 treatment, and admissions to drug treatment facilities in California more than doubled from
9 2006/2007 to 2010/2011. Addiction treatment centers indicate that many of their patients – for one
10 facility in northern California, up to 90% – started on legal opioid prescriptions.

11 296. The explosion in opioid prescriptions and use caused by Defendants has led to a
12 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
13 overdoses and deaths as well as devastating social and economic consequences. This public health
14 crisis is a public nuisance because it “is injurious to health” and interferes “with the comfortable
15 enjoyment of life and property” (Civ. Code, § 3479) and because it affects “entire communit[ies]”
16 and “neighborhood[s]” and “any considerable number of persons” (id., § 3480). The effects of each
17 Defendant’s deceptive marketing and distribution scheme are catastrophic and are only getting
18 worse.

19 297. There is little doubt that each Defendant’s deceptive marketing and distribution
20 scheme has precipitated this public health crisis in California, including Alameda County, by
21 dramatically increasing opioid prescriptions and use. An oversupply of prescription opioids has
22 provided a source for illicit use or sale of opioids (the supply), while the widespread use of opioids
23 has created a population of patients physically and psychologically dependent on them (the
24 demand). And when those patients can no longer afford or legitimately obtain opioids, they often
25 turn to the street to buy prescription opioids or even heroin.

26 298. The effects of Defendants’ deceptive marketing and distribution scheme has further
27 impacted Plaintiff in a foreseeable way such that Alameda County must devote increased resources
28 to the burden of the addicted homeless who commit drug and property crimes, to feed their

1 addiction. For example, tax dollars are required to maintain public safety of places where the
 2 addicted homeless attempt to congregate, including parks, schools and public lands. Tax dollars are
 3 required to fight the infectious diseases frequently carried by addicts, and particularly the addicted
 4 homeless. Hepatitis B and C, HIV, sexually transmitted disease and methicillin-resistant
 5 *Staphylococcus aureus* (MRSA) are spread by opioid abuse.

6 299. Unscrupulous opioid rehabilitation businesses, including certain DOE Defendants,
 7 have recruited addicts nationally with false and misleading promises of the medically supervised
 8 rehabilitation to help addicts overcome their addiction. The promotion claimed that there was
 9 effective rehabilitation available in beautiful California communities. These for-profit
 10 rehabilitation businesses failed to provide proper rehabilitation facilities. Investigations revealed
 11 that many have provided substandard care including use of physicians who have had their license
 12 revoked, operating staffs which do not actually supervise patients, and facilities that do not operate
 13 programs for addicts. Instead these facilities bring addicts to California, provide substandard care
 14 as long as there are third party payments available, and then throw them out of the facilities to be
 15 homeless. These addicts brought to California by the substandard rehab industry, have further
 16 contributed to the public's burden by discharging addicted homeless into the community who
 17 require further care and rehabilitation at the public's expense, and who commit crimes in California
 18 in order to further feed their addiction. The manufacturer and distributor Defendants were aware at
 19 all relevant times when they deceptively marketed their products as non-addictive that such
 20 addiction would be highly difficult to overcome. Defendants knew or should have known that
 21 municipalities, including Alameda County, would bear the burden of costs associated with
 22 rehabilitation business of all types.

23 300. The role of Defendants' deceptive marketing and distribution scheme in causing this
 24 public health crisis has been well established. In her May 2014 testimony to the Senate Caucus on
 25 International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
 26 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have
 27 contributed to the severity of the current prescription drug abuse problem." And in August 2016,
 28 the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy

1 marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that opioids
2 are not addictive when prescribed for legitimate pain.” California doctors, addiction treatment
3 specialists, and law enforcement and public health officials confirm that prescription opioids
4 lawfully prescribed by doctors have fueled this epidemic.

5 301. Absent each Defendant’s deceptive marketing scheme and improper distribution,
6 opioid prescribing, use, misuse, abuse, and addiction would not have become so widespread, and
7 the opioid epidemic that now exists would have been averted or much less severe.

8 302. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
9 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
10 claims, and by improperly distributing prescription opioids as set forth herein, Defendants have not
11 only engaged in false advertising, they have also created or assisted in the creation of a public
12 nuisance. Every act of malfeasance committed by each Defendant since the late 1990s to the
13 present is part of its deceptive marketing and distribution scheme and subjects that Defendant to
14 liability for public nuisance because there is no statute of limitations for a public nuisance claim.
15 *See* Cal. Civ. Code § 3490 (“No lapse of time can legalize a public nuisance, amounting to an actual
16 obstruction of public right”); *Wade v. Campbell*, (1962) 200 Cal.App.2d 54, 61 (“the maintenance
17 of a public nuisance may not be defended on the ground of laches or the statute of limitations”).

18 303. Accordingly, Defendants’ conduct, both individually and collectively, has violated
19 and continues to violate the False Advertising Law, Cal. Bus. & Prof. Code, §§ 17500 *et seq.*, and
20 the Public Nuisance Law, Cal. Civ. Code, §§ 3479 and 3480. Alameda County does not seek to
21 limit the ability of doctors in California to prescribe opioids. Alameda County does not ask this
22 Court to weigh the risks and benefits of long-term opioid use. Instead, Alameda County seeks an
23 order requiring Defendants to cease their unlawful promotion and distribution of opioids, to correct
24 their misrepresentations, and to abate the public nuisance they have created. To redress and punish
25 Defendants’ previous and current violations of law that cause and continue to cause harm to
26 Alameda County, Plaintiff seeks a judgment requiring Defendants to pay civil penalties, and any
27 fees or costs permitted under law.

28 304. By this action, Alameda County further seeks to recoup tax dollars spent already for

1 the consequences of Defendants' wrongful conduct in causing the opioid epidemic and crisis and
2 its impact on this county and its communities, and to abate the opioid nuisance so Alameda County
3 will not be required to spend further taxpayer dollars on the epidemic and crisis wrought by
4 Defendants' wrongful conduct as alleged herein.

5 305. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
6 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
7 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
8 California spiked by 34% from 2011 to 2013.

9 306. Opioid abuse also contributes to a range of social problems including physical and
10 mental consequences, crime, delinquency, and mortality. Other adverse social outcomes include
11 child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage,
12 unemployment, and despair. More and more Alameda County resources are needed to combat these
13 problems. Alameda County faces a growing employment staffing problem, as critical services such
14 as social services and victims' assistance programs have experienced high rates of employee
15 turnover due to the opioid-related nature of the work. The prescription opioid crisis also diminishes
16 Alameda County's available workforce, decreases productivity, increases poverty, and requires
17 greater governmental expenditures by Alameda County.

18 307. The prescription opioid crisis has directly financially injured Alameda County. The
19 crisis has led to an increased demand for, *inter alia*, security services (such as police, EMS,
20 detention), child protective services, health services, clean-up services, and legal services. Alameda
21 County has also had to hire additional staff and expend additional resources to manage the demand.

22 308. Alameda County's medical services have seen an increase in opioid-related health
23 problems among Alameda County residents, including, but not limited to, infants born with opioid-
24 related medical conditions. This has resulted in increased demand, difficulty retaining staff, and
25 increased expenses.

26 309. Alameda County has also suffered substantial financial damages in the form of lost
27 productivity of Alameda County employees and residents, lost economic activity, lost reputation
28 and good will, and the lost opportunity for growth. These damages have been suffered and continue

1 to be suffered directly by Alameda County.

2 310. Many patients who become addicted to opioids will lose their jobs. Some will lose
3 their homes and their families. Some will get treatment and fewer will successfully complete it;
4 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
5 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
6 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
7 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
8 drug transactions; or dying from opioid-induced heart or neurological disease.

9 311. Alameda County also has suffered substantial financial damages in the form of lost
10 taxes paid by its residents and businesses as a result of lost earnings and productivity.

11 312. While the use of opioids has taken an enormous toll on Alameda County and its
12 residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11
13 billion in revenue for drug companies like the Defendants. Indeed, on information and belief, each
14 Defendant experienced a material increase in sales, revenue, and profits from the unlawful conduct
15 described above.

16 **I. The Statutes of Limitations Are Tolloed and Defendants Are Estopped from**
17 **Asserting Statutes of Limitations As Defenses**

18 313. Defendants' conduct has continued from the early 1990s through today and remains
19 ongoing. The continued tortious and unlawful conduct by the Defendants has caused a repeated or
20 continuous injury. The damages have not occurred all at once but have continued to occur and have
21 increased as time progresses. The tort is not completed nor have all the damages been incurred until
22 the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The
23 public nuisance remains unabated.

24 314. Defendants are equitably estopped from relying upon a statute of limitations defense
25 because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently
26 assure the public that they were undertaking efforts to comply with their obligations under the
27 controlled substances laws, all with the goal of continuing to generate profits.

28 315. For example, a Cardinal Health executive claimed that it uses "advanced analytics"

1 to monitor its supply chain, and assured the public it was being “as effective and efficient as
2 possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁸⁶

3 316. Similarly, McKesson publicly stated that it has a “best-in-class controlled substance
4 monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about
5 curbing the opioid epidemic in our country.”⁸⁷

6 317. Defendants, through their trade associations, filed an amicus brief that represented
7 that Defendants took their duties seriously, complied with their statutory and regulatory
8 responsibilities, and monitored suspicious orders using advanced technology.⁸⁸

9 318. Defendants purposely concealed their wrongful conduct, including by assuring the
10 public and governmental authorities that they were complying with their obligations and were
11 acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their
12 behavior by providing the public with false information about opioids and have continued to use
13 Front Groups and third parties to minimize the risks of Defendants’ conduct. Defendants’ conduct
14 is continuing to this day.

15 319. Defendants have also concealed and prevented discovery of information, including
16 data from the ARCOS database, which will confirm their identities and the extent of their wrongful
17 and illegal activities.

18 320. Defendants also lobbied Congress and actively attempted to halt DEA investigations
19 and enforcement actions and to subvert the ability of agencies to regulate their conduct.⁸⁹ As a
20 result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a

21
22 ⁸⁶ Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: “No*
23 *One Was Doing Their Job,”* Wash. Post (Oct. 22, 2016), available at
[https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
24 [of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html)
25 [7b6c1998b7a0_story.html](https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html) (last accessed December 21, 2017)

26 ⁸⁷ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb*
27 *Opioid Abuse*, Wash. Post, (Dec. 22, 2016), available at
28 [https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html)
[industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html](https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html) (last accessed December 21,
2017).

⁸⁸ Br. for Healthcare Distribution Mgmt. Ass’n and Nat’l Ass’n of Chain Drug Stores as Amici Curiae in
Support of Neither Party, Case No. 15-1335, 2016 WL 1321983, at *3-4, *25 (filed in the 2d Cir. Apr. 4,
2016).

⁸⁹ See Higham and Bernstein, *supra* note 53.

1 distributor's license was raised.

2 321. In addition, the Defendants fraudulently attempted to convince the public that they
3 were complying with their legal obligations and working to curb the opioid epidemic.

4 322. Because the Defendants concealed the facts surrounding the opioid epidemic,
5 Alameda County did not know if the existence or scope of the Defendants' misconduct, and could
6 not have acquired such knowledge earlier through the exercise of reasonable diligence.

7 323. Defendants intended that their false statements and omissions be relied upon,
8 including by Alameda County, and its residents.

9 324. Defendants knew of their wrongful acts and had material information pertinent to
10 their discovery, but concealed that information from the public, including Alameda County, and its
11 residents. Only Defendants knew of their widespread misinformation campaign and of their
12 repeated, intentional failures to prevent opioid diversion.

13 325. Defendants cannot claim prejudice due to a late filing because this suit was filed
14 upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the
15 opioid crisis have only recently come to light.

16 326. Defendants had actual knowledge that their conduct was deceptive, and they
17 intended it to be deceptive.

18 327. Alameda County was unable to obtain vital information regarding these claims
19 absent any fault or lack of diligence on Alameda County's part.

20 **V. FACTS PERTAINING TO DEFENDANTS' CONSPIRACY**

21 **A. The Marketing Scheme**

22 328. Knowing that their opioids were highly addictive, ineffective, and unsafe for the
23 treatment of long-term, chronic pain, non-acute, and non-cancer pain, Manufacturer Defendants
24 conspired with the Front Groups and KOLs described above to engage in a scheme to increase their
25 profits and sales unlawfully, and grow their share of the prescription painkiller market, through
26 repeated and systematic misrepresentations about the safety and efficacy of opioids for treating
27 long-term, chronic pain. Through their personal relationships, the members of this marketing
28 scheme had the opportunity to form and take actions in furtherance of their common purpose. The

1 Manufacturer Defendants' substantial financial contribution to the marketing scheme, and the
2 advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

3 329. The Manufacturer Defendants, through their marketing scheme, concealed the true
4 risks and dangers of opioids from the medical community and the public, including Plaintiff, and
5 made misleading statements and misrepresentations about opioids that downplayed the risk of
6 addiction and exaggerated the benefits of opioid use. The misleading statements included, among
7 others, that: (a) addiction is rare among patients taking opioids for pain; (b) addiction risk can be
8 effectively managed; (c) symptoms of addiction exhibited by opioid patients are actually symptoms
9 of an invented condition the Manufacturer Defendants named "pseudoaddiction"; (d) withdrawal
10 is easily managed; (e) increased dosing presents no significant risks; (f) long-term use of opioids
11 improves function; (g) the risks of alternative forms of pain treatment are greater than the adverse
12 effects of opioids; (h) use of time-released dosing prevents addiction; and (i) abuse-deterrent
13 formulations provide a solution to opioid abuse.

14 330. The marketing scheme devised, implemented and conducted by the Manufacturer
15 Defendants was designed to ensure that they unlawfully increased their sales and profits through
16 concealment and misrepresentations about the addictive nature and effective use of their drugs. The
17 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common purpose
18 and perpetuated the marketing scheme, including through the unbranded promotion and marketing
19 network as described above.

20 331. There was regular communication between the Manufacturer Defendants, Front
21 Groups and KOLs, in which information was shared, misrepresentations coordinated, and payments
22 exchanged. Typically, the coordination, communication and payment occurred, and continues to
23 occur, through the repeated and continuing use of the wires and mail in which the Manufacturer
24 Defendants, Front Groups, and KOLs share information regarding overcoming objections and
25 resistance to the use of opioids for chronic pain. The Manufacturer Defendants, Front Groups and
26 KOLs functioned as a continuing unit for the purpose of implementing the marketing scheme, and
27 each agreed and took actions to hide the scheme and continue its existence.

28 332. At all relevant times, the Front Groups were aware of the Manufacturer Defendants'

1 conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front
2 Group also knew, but did not disclose, that the other Front Groups were engaged in the same
3 marketing scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the
4 Manufacturer Defendants, Front Groups and KOLs' unlawful fraud, the Front Groups would have
5 had incentive to disclose the deceit by the Manufacturer Defendants and the marketing scheme to
6 their members and constituents. By failing to disclose this information, Front Groups perpetuated
7 the marketing scheme, and reaped substantial benefits.

8 333. At all relevant times, the KOLs were aware of the Manufacturer Defendants'
9 conduct, were knowing and willing participants in that conduct, and reaped benefits from that
10 conduct. The Manufacturer Defendants selected KOLs solely because they favored the aggressive
11 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the KOLs
12 become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the
13 benefits of using opioids to treat chronic pain, repaying the Manufacturer Defendants by advancing
14 their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front
15 Groups were engaged in the same marketing scheme, to the detriment of consumers, prescribers,
16 and Plaintiff. But for the Manufacturer Defendants, Front Groups and KOLs' unlawful conduct,
17 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and the
18 marketing scheme, and to protect their patients and the patients of other physicians. By failing to
19 disclose this information, KOLs furthered the marketing scheme, and reaped substantial benefits.

20 334. As public scrutiny and media coverage focused on how opioids ravaged
21 communities in California and throughout the United States, the Front Groups and KOLS did not
22 challenge the Manufacturer Defendants' misrepresentations, seek to correct their previous
23 misrepresentations, terminate their role in the marketing scheme, nor disclose publicly the risks of
24 using opioids for chronic pain.

25 335. The Manufacturer Defendants, Front Groups and KOLs engaged in certain discrete
26 categories of activities in furtherance of the marketing scheme. As described herein, the
27 Manufacturer Defendants, Front Groups and KOLs' conduct in furtherance of the common purpose
28 of the marketing scheme involved: (a) misrepresentations regarding the risk of addiction and safe

1 use of prescription opioids for long-term chronic pain (described in detail above); (b) lobbying to
2 defeat measures to restrict over-prescription; (c) efforts to criticize or undermine CDC guidelines;
3 and (d) efforts to limit prescriber accountability.

4 336. In addition to disseminating misrepresentations about the risks and benefits of
5 opioids, Manufacturer Defendants, Front Groups and KOLs also furthered their common purpose
6 by criticizing or undermining CDC guidelines. Manufacturer Defendants, Front Groups and KOLs
7 criticized or undermined the CDC Guidelines which represented “an important step – and perhaps
8 the first major step from the federal government - toward limiting opioid prescriptions for chronic
9 pain.”

10 337. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized
11 the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not
12 transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest
13 of the individuals who participated in the construction of these guidelines.”

14 338. The AAPM criticized the prescribing guidelines in 2016, through its immediate past
15 president, stating “that the CDC guideline makes disproportionately strong recommendations based
16 upon a narrowly selected portion of the available clinical evidence.”

17 339. The Manufacturer Defendants alone could not have accomplished the purpose of the
18 marketing scheme without the assistance of the Front Groups and KOLs, who were perceived as
19 “neutral” and more “scientific” than the Manufacturer Defendants themselves. Without the work
20 of the Front Groups and KOLs in spreading misrepresentations about opioids, the marketing
21 scheme could not have achieved its common purpose.

22 340. The impact of the marketing scheme remains in place—i.e., the opioids continue to
23 be prescribed and used for chronic pain throughout Alameda County, and the epidemic continues
24 to injure Plaintiff, and consume the resources of Plaintiff’s health care and law enforcement
25 systems.

26 341. As a result, it is clear that the Manufacturer Defendants, the Front Groups, and the
27 KOLs were each willing participants in the marketing scheme, had a common purpose and interest
28 in the object of the scheme, and functioned within a structure designed to effectuate the scheme’s

1 purpose.

2 **B. The Distribution Scheme**

3 342. Faced with the reality that they will now be held accountable for the consequences
4 of the opioid epidemic they created, members of the industry resort to “a categorical denial of any
5 criminal behavior or intent.”⁹⁰ Defendants’ actions went far beyond what could be considered
6 ordinary business conduct. For more than a decade, the Distributor Defendants worked together in
7 an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-
8 competitive, with the common purpose and achievement of vastly increasing their respective profits
9 and revenues by exponentially expanding a market that the law intended to restrict.

10 343. Knowing that dangerous drugs have a limited place in our society, and that their
11 dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse
12 and addiction causes to individuals, society and governments, California enacted California
13 Business and Professions Code §§ 4164 and 4169.1, and adopted 16 CCR § 1782, which require
14 Defendants to report suspicious orders of dangerous drugs subject to abuse and to maintain systems
15 to detect and report such activity.

16 344. If morality and the law did not suffice, competition dictates that the Distributor
17 Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed,
18 if a manufacturer or distributor could gain market share by reporting a competitor’s illegal behavior
19 (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct
20 dictates that it would do so.

21 345. The Distributor Defendants’ scheme required the participation of all. If any one
22 member broke rank, its compliance activities would highlight deficiencies of the others, and the
23 artificially high quotas they maintained through their scheme would crumble. But, if all the
24 members of the enterprise conducted themselves in the same manner, it would be difficult for state
25 authorities or the DEA to go after any one of them. Accordingly, through the connections they
26

27 ⁹⁰ McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal
28 Government, McKesson, available at <http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response> (last visited Apr. 21, 2018).

made as a result of their participation in the Healthcare Distribution Alliance (“HDA”), the Distributor Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances.” But, privately, the Distributor Defendants refused to act. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants’ duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Yet, the Distributor Defendants apparently all found the same profit-maximizing balance – intentionally remaining silent to ensure the largest possible financial return.

346. As described above, at all relevant times, the Distributor Defendants conspired together for the purpose of unlawfully increasing sales, revenues and profits. In support of this common purpose and fraudulent scheme, the Distributor Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

347. At all relevant times, as described above, the Distributor Defendants exerted control over, conducted and/or participated in distribution scheme by fraudulently claiming that they were complying with their duties under California law to report suspicious orders and to maintain systems to detect and report such activity.

348. While participating in their distribution scheme, Distributor Defendants applied political pressure at the state and federal level to limit regulators’ ability to quickly and effectively police suspicious drug shipments. As part of these efforts, the Distributor Defendants lobbied Congress to pass the “Ensuring Patient Access and Effective Drug Enforcement Act.”⁹¹

⁹¹ *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, available at <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/>

349. The Distributor Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the California Board of Pharmacy and the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the Distributor Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the California Board of Pharmacy and the DEA in their mandatory reports.

VI. MISCELLANEOUS FACTUAL ALLEGATIONS

350. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

351. Defendants' causal role in the opioid epidemic was not broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

352. Each Defendant's conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under California Business & Professions Code § 17536.

(last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), available at https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html (last accessed December 21, 2017); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), available at https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html (last accessed December 21, 2017); Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), available at <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-> (last accessed December 21, 2017).

1 353. As a members of the boards of various Purdue entities, the Sacklers oversaw all
2 aspects of Purdue's marketing and promotion of opioid products. As board members who were
3 personally active in directing Purdue's operations, the Sackler Defendants knew, or should have
4 known, of Purdue's deceptive marketing tactics of opioid products.

5 354. The Sackler Defendants also were aware of specific examples of deceptive
6 marketing through receipt of call note reviews in their capacities as board members. On information
7 and belief, the Sacklers received reports of opioid overdoses and reports of misuse and abuse in
8 their capacities as board members. Adverse event reports circulated to the Sacklers included reports
9 of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin.

10 355. The Sackler Defendants were personally aware that: (1) OxyContin was being
11 prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just
12 through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and
13 diversion; and (4) OxyContin was wrongly, and dangerously, perceived as safer than morphine.

14 356. By 2006, prosecutors at the United States Department of Justice found damning
15 evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers
16 voted that the Purdue Frederick Company should plead guilty to a felony for misbranding
17 OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse
18 events and side effects than other pain medications.

19 357. As members of the family that owns Purdue, the Sackler Defendants personally
20 benefitted from the success of OxyContin. At various points, as directors, they approved the
21 distribution of funds from Purdue to shareholders, including themselves and their extended family.

22 358. Since at least 1999, the Sackler Defendants were aware of potential liability for
23 Purdue, as well as those acting in concert with Purdue, because of the addictive nature of Oxycontin.
24 Intending to shield the proceeds of their wrongdoing from creditors, the Sackler Defendants have
25 stripped Purdue each and every year of hundreds of millions of dollars of profits from the sale of
26 Oxycontin and other opioid-containing medications. All such transfers were and are fraudulent and
27 all such transferred funds should be clawed back from the Sackler Defendants in order to satisfy
28 the opioid related liabilities of the companies from which they were transferred.

359. Plaintiff is informed and believes that due to the billions of dollars in profits that have been distributed to the Sackler Defendants since the 1980's, Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff and to the multitude of other plaintiffs that have commenced litigation against Purdue nationwide for its role in creating the opioid epidemic. Accordingly, the Sackler Defendants have knowingly participated in the wrongdoing of Purdue, as well as knowingly profited and received the benefits of that wrongdoing.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Public Nuisance – Cal. Civ. Code §§ 3479-3480 – Against All Defendants)

360. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 359 above as if set forth fully herein.

361. California Civil Code § 3479 provides that “anything which is injurious to health ... or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property ... is a nuisance.”

362. California Civil Code § 3480 defines a “public nuisance” as “one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal.”

363. California Civil Code § 3490 states that “no lapse of time can legalize a public nuisance, amounting to an actual obstruction of public right.”

364. Pursuant to § 731 of the California Code of Civil Procedure, this action is brought by Alameda County to abate the public nuisance created by the Defendants.

365. Each Defendant, acting individually and in concert, has created or assisted in the creation of a condition that is injurious to the health and interferes with the comfortable enjoyment of life and property of entire communities or neighborhoods or of any considerable number of persons in Alameda County in violation of California Civil Code §§ 3479 and 3480.

366. The public nuisance is substantial and unreasonable. Defendants’ actions caused and continue to cause the public health epidemic described above in Alameda County, and that harm outweighs any offsetting benefit.

1 367. Defendants knew and should have known that their promotion and distribution of
2 opioids was false and misleading and that their deceptive marketing scheme would create or assist
3 in the creation of the public nuisance—i.e., the opioid epidemic.

4 368. Defendants' actions were, at the very least, a substantial factor in opioids becoming
5 widely available and widely used. Defendants' actions were, at the very least, a substantial factor
6 in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
7 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become
8 so widespread, and the opioid epidemic that now exists would have been averted or much less
9 severe.

10 369. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
11 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
12 can be abated.

13 370. Each Defendant is liable for public nuisance because its conduct at issue is
14 intentional, unreasonable, and unlawful, and has created an epidemic which annoys, injures or
15 endangers the safety, health, morals, comfort, or repose of a considerable number of people in
16 Alameda County. Defendants' conduct is also indecent or offensive to the senses, and constitutes
17 an obstruction to the free use of property sufficient to constitute an interference with the people of
18 Alameda County's comfortable enjoyment of life or property.

19 371. As more fully alleged in the preceding Paragraphs of this Complaint, Defendants'
20 intentional and deliberately deceptive marketing strategy to expand opioid use, together with their
21 equally deliberate efforts to evade restrictions on opioid distribution has caused substantial and
22 unreasonable interference with Alameda County and its residents' public rights, including, but not
23 limited to, the public's right to health, safety, welfare, peace, comfort, convenience, and ability to
24 be free from disturbance and reasonable apprehension of danger to person or property.

25 372. Specifically, Manufacturer Defendants intentionally, unlawfully, and unreasonably
26 interfered with Alameda County and its residents' public rights by, *inter alia*, engaging in a
27 promotion and marketing scheme that pushed the use of opioids for indications not federally
28 approved, and by circulating false and misleading information concerning their risks, benefits, and

1 superiority, and/or downplaying or omitting the risk of addiction arising from their use. In so doing,
2 Manufacturer Defendants failed to comply with federal law.

3 373. Defendants have also unlawfully and intentionally distributed opioids or caused
4 opioids to be distributed within and without Alameda County absent effective controls against
5 diversion. Such conduct was illegal, and proscribed by statute and regulation. Defendants' failures
6 to maintain effective controls against diversion include Defendants' failure to effectively monitor
7 for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

8 374. Defendant's unreasonable interference with Alameda County residents' public
9 rights include, but are not limited to, the effects of addiction, abuse, elevated crime, deaths, and
10 increased expenditures to combat and address these harms. Alameda County has also made
11 payments for opioid addiction treatment. These damages have been suffered and continue to be
12 suffered directly by Alameda County and its residents.

13 375. Defendants' actions have also created a palpable climate of fear, distress,
14 dysfunction and chaos among residents of Alameda County where opioid diversion, abuse, and
15 addiction are prevalent and where diverted opioids are used frequently. Specifically, Defendants
16 conduct has caused, among other things, (a) routine separation of children from their parents who
17 have fallen victim to easy access to opioids and/or related crime; (b) children to have easy access
18 and to become addicted to opioids; (c) residents to endure both the emotional and financial costs of
19 caring for loved ones addicted to or injured by opioids; (d) increased crime and/or destruction of
20 public spaces and property; (e) property crimes throughout Alameda County; (f) employers to lose
21 the value of productive and healthy employees; (g) increased public health and safety costs; (h) a
22 decrease in property values within Alameda County; and (g) a decrease in tax revenues for Alameda
23 County.

24 376. The impact of Defendants' conduct on Alameda County is of a continuing nature.
25 Defendants' conduct will undoubtedly continue to cause long-lasting effects on their public rights.

26 377. Defendants knew or should have known that their actions would lead to the national
27 opioid epidemic and to the resulting injuries to the public rights of Alameda County.

28 378. Alameda County has sustained a special and peculiar injury because its damages

1 include, *inter alia*, health service expenditures, public safety expenditures, payment of opioid
2 addiction treatment, decreased tax revenues and property values, and other costs related to opioid
3 addiction treatment and overdose prevention.

4 379. The externalized risks associated with Defendants' nuisance-creating conduct as
5 described herein greatly exceed the internalized benefits.

6 380. Defendants' actions are a direct and proximate contributing cause of the opioid
7 epidemic and the injuries to the public rights of Alameda County and its residents.

8 381. Defendants, individually and collectively, are at the very least, a substantial factor
9 in causing the national opioid epidemic and of the injuries to Alameda County and its residents.

10 382. The injuries to the public rights of Alameda County and its residents are indivisible
11 injuries.

12 383. Defendants' manufacture, marketing, distribution, and sale of prescription opioids,
13 if unabated, will continue to cause an unreasonable interference with public rights of Alameda
14 County and its residents.

15 384. Defendants' conduct is ongoing and persistent, and Alameda County seeks all
16 damages flowing from Defendants' conduct. Alameda County seeks economic losses (direct,
17 incidental, and/or consequential pecuniary losses) resulting from Defendants' illegal and wrongful
18 conduct described above. Alameda County does not seek damages for the wrongful death, physical
19 personal injury, or emotional distress caused by Defendants' actions.

20 385. Pursuant to Code of Civil Procedure § 731, Alameda County requests an order
21 providing for abatement of the public nuisance that Defendants created or assisted in the creation
22 of, and enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

23 **SECOND CAUSE OF ACTION**
24 **(Fraud – Against All Defendants)**

25 386. Plaintiff realleges and incorporates herein by reference each and every allegation in
26 paragraphs 1 through 385 above as if set forth fully herein.

27 387. Plaintiff realleges and incorporates by reference the foregoing allegations as if set
28 forth herein

1 388. The Defendants made fraudulent misrepresentations and omissions of material fact.
2 Defendants' knowing deceptions during the relevant period, more fully described in this Complaint,
3 were intended to induce reliance.

4 389. Those misrepresentations and omissions were known to be untrue by the
5 Defendants, or were recklessly made.

6 390. As alleged herein, the Manufacturer Defendants engaged in false representations
7 and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, the
8 dangers of abuse, and the risks of addiction.

9 391. As alleged herein, Defendants made false statements and/or omissions regarding
10 their compliance with state law regarding their duties to prevent diversion, their duties to monitor,
11 report and halt suspicious orders, and/or concealed their noncompliance with these requirements.
12 Defendants also failed to disclose the prevalence of diversion of controlled substances, including
13 opioids, within Alameda County.

14 392. Defendants made those misrepresentations and omissions in an intentional effort to
15 deceive Alameda County and its residents, despite the Defendants' knowledge of the dangers of
16 such use of prescription opioids.

17 393. In addition and independently, Defendants had a duty not to deceive Plaintiff
18 because Defendants had in their possession unique material knowledge that was unknown, and not
19 knowable, to Plaintiff, Plaintiff's agents, physicians, and the public.

20 394. The Defendants continued making those misrepresentations, and failed to correct
21 those material omissions, despite repeated regulatory settlements and publications demonstrating
22 the false and misleading nature of the Defendants' omissions and/or claims.

23 395. While Defendants had a duty to disclose the above-referenced material facts, they
24 nevertheless concealed them. These false representations and concealed facts were material to the
25 conduct and actions at issue. Defendants made these false representations and concealed facts with
26 knowledge of the falsity of their representations and did so with the intent of misleading Alameda
27 County, its residents, the public, and persons on whom these entities relied.

28 396. Defendants intended and had reason to expect under the operative circumstances

1 that Plaintiff, Plaintiff's agents, physicians, the public, and persons on whom Plaintiff and its agents
2 relied would be deceived by Defendants' statements, concealments, and conduct as alleged herein
3 and that these entities would act or fail to act in reasonable reliance thereon.

4 397. Alameda County, its residents, and others, did in fact rightfully, reasonably, and
5 justifiably rely on Defendants' representations and/or concealments, both directly and indirectly.

6 398. For instance, doctors, including those serving Alameda County and its residents,
7 relied on the Defendants' misrepresentations and omissions in prescribing opioids for chronic pain
8 relief. Patients, including residents of Alameda County, relied on the Defendants'
9 misrepresentations and omissions in taking prescription opioids for chronic pain relief.

10 399. Also, as a result of these representations and/or omissions, Plaintiff proceeded under
11 the misapprehension that the opioid crisis was simply a result of conduct by persons other than
12 Defendants. As a consequence, these Defendants prevented Plaintiff from a more timely and
13 effective response to the opioid crisis.

14 400. Defendants' misconduct alleged in this case is ongoing and persistent.

15 401. Alameda County has experienced an unprecedented opioid addiction and overdose
16 epidemic leading to increased costs for, *inter alia*, emergency services, treatment services, security
17 services, and lost productivity to Alameda County's workforce.

18 402. The injuries alleged by Plaintiff herein were sustained as a direct and proximate
19 result of Defendants' fraudulent conduct.

20 403. As a direct and foreseeable consequence of Defendants' fraud, Alameda County has
21 incurred and continues to incur damages in an amount to be proved at trial consisting of costs for
22 opioid addiction treatment and its secondary consequences in excess of those Alameda County
23 would have otherwise incurred.

24 404. As alleged herein, Defendants' fraud was willful, malicious, oppressive, and
25 fraudulent, entitling Alameda County to punitive damages.

26 **THIRD CAUSE OF ACTION**
27 **(Negligence – Against All Defendants)**

28 405. Plaintiff realleges and incorporates herein by reference each and every allegation in

1 paragraphs 1 through 404 above as if set forth fully herein.

2 406. To establish actionable negligence in California, Plaintiff must show a duty, a breach
3 of that duty, and injury resulting proximately therefrom.

4 407. Defendants have a duty to exercise reasonable care under the circumstances, in light
5 of the risks. This includes a duty not to cause foreseeable harm to others. In addition, these
6 Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had,
7 and still have, a duty to exercise reasonable care to prevent the threatened harm.

8 408. In addition, Defendants had a duty not to breach the standard of care established
9 under California law, including 16 CCR § 1782 and California Business and Professions Code §§
10 4164 and 4169.1, which require Defendants to report suspicious orders of dangerous drugs subject
11 to abuse, and to develop and maintain systems to detect and report such activity.

12 409. Defendants voluntarily undertook a legal duty to prevent the diversion of
13 prescription opioids by engaging in the distribution of prescription opioids and by making public
14 promises to prevent the diversion of prescription opioids.

15 410. Defendants knew of the serious problem posed by prescription opioid diversion and
16 were under a legal obligation to take reasonable steps to prevent diversion.

17 411. Defendants knew of the highly addictive nature of prescription opioids and of the
18 high likelihood of foreseeable harm to patients and communities, including Alameda County, from
19 prescription opioid diversion.

20 412. Defendants had a legal duty to exercise reasonable and ordinary care and skill and
21 in accordance with applicable standards of conduct in advertising, marketing, selling, and
22 distributing opioid products in a safe manner to minimize the risk of addiction in patients and
23 resultant harm to those patients, their families and their communities, and to taxpayers and
24 municipal government such as Alameda County which must incur enormous expenditures for
25 prevention, treatment, emergency response and law enforcement costs and other foreseeable costs
26 related to the need to address the consequences of a large number of residents that become addicted
27 to opioids as a result of Defendants' conduct.

28 413. As described throughout the Complaint, Defendants breached their duties to

1 exercise due care in the business of wholesale distribution of dangerous opioids by failing to
2 monitor for, failing to report, and filling highly suspicious orders time and again.

3 414. As described throughout the Complaint, in language expressly incorporated herein,
4 Defendants misrepresented their compliance with their duties under the law and concealed their
5 noncompliance and shipments of suspicious orders of opioids to Alameda County and destinations
6 from which they knew opioids were likely to be diverted into Alameda County, in addition to other
7 misrepresentations alleged and incorporated herein.

8 415. The Manufacturer Defendants breached their duty to Plaintiff by deceptively
9 marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the
10 purported benefits of long-term use of opioids for the treatment of chronic pain.

11 416. Manufacturer Defendants knew or should have known, that their affirmative
12 misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing
13 narcotic drugs created an unreasonable risk of harm. The Defendants' sales data, reports from sales
14 representatives, and internal documents, should have put them on notice that such harm was not
15 only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively
16 withhold or downplay information about the dangers of opioids from Plaintiff, physicians, patients,
17 and the public.

18 417. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct
19 was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

20 418. Defendants' misconduct alleged in this case is ongoing and persistent.

21 419. Defendants acted with actual malice in repeatedly breaching their duties—i.e., they
22 acted with a conscious disregard for the rights and safety of other persons, and said actions had a
23 great probability of causing substantial harm.

24 420. As is described throughout this Complaint, Defendants acted without even slight
25 diligence or scant care, and with indifference, and were negligent in a very high degree,
26 disregarding the rights and safety of other persons, and said actions have a great probability of
27 causing substantial harm.

28 421. Defendants' misconduct further meets the criteria set forth in *Rowland v. Christian*

(1968) 69 Cal.2d 108, 113, for imposing on Defendants a duty to exercise ordinary care and skill in the in advertising, marketing, selling and distributing opioid products in a safe manner to minimize the risk of addiction in patients and resultant harm to those patients, their families and their communities, and to taxpayers and municipal government such as Alameda County, including, but not limited to, the following:

- a. Foreseeability of harm to Alameda County: Defendants were aware or reasonably should have been aware of the risk of addiction of a large number of patients in places such as Alameda County, and need for their care and treatment and in handling other consequences of their addiction and that such costs would be borne by local governments such as Alameda County;
- b. Degree of certainty Alameda County suffered harm: Alameda County has suffered enormous harm and costs in addressing treatment of addicted patients, including but not limited to expenditures for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences of a large number of residents that become addicted to opioids as a result of Defendants' conduct;
- c. Closeness of connection between Alameda County's harm: The explosion of opioid addiction and the presence of opioid addicted patients in Alameda County as a result of Defendants' conduct has resulted in expenditures directly for prevention, treatment, emergency response and law enforcement costs and other foreseeable costs related to the need to address the consequences;
- d. Moral blame attached to Defendants' conduct: Defendants' knew or should have known that their wrongful conduct, actions and omissions would result in an explosion of patients who would become addicted to opioids, and that a vast opioid epidemic would result from the prescription of opioids to tens of millions

1 of patients nationwide, including within Alameda County, and that the costs
2 would be borne by the state, county and municipal local governments, while
3 Defendants profited tens of billions of dollars collectively from the widespread
4 use of prescription opioid products;

5
6 e. Policy of preventing future harm: As a direct and foreseeable result of
7 Defendants' wrongful conduct, the opioid epidemic and crisis has and continues
8 to occur on a vast scale both nationally and locally in places such as Alameda
9 County resulting in tremendous harm and cost to the patients, their families and
10 the communities in dealing with this epidemic and crisis, and there is a need to
11 ensure that the costs of such wrongful conduct is borne by Defendants so that
12 parties contemplating such or similar conduct in the future know they will be
13 held responsible for such harm;

14
15 f. Extent of burden to Defendants: There is no burden to Defendants in that state
16 and other law precludes them from engaging in the conduct alleged herein, and
17 there is no burden from precluding Defendants from profiting from their
18 wrongful conduct and operating within the confines of the law in advertising,
19 marketing, selling and distributing opioid products in a safe manner to minimize
20 the risk of addiction in patients and resultant harm to those patients, their
21 families and their communities, and to taxpayers and municipal government
22 such as Plaintiff Alameda County; and

23
24 g. Consequences to the community of imposing a duty to exercise care with
25 resulting liability for breach: Imposing a duty to not engage in Defendants'
26 wrongful conduct of advertising, marketing, selling and distributing opioid
27 products in an unsafe manner would minimize the risk of addiction in patients,
28

1 and liability for a breach of this duty would benefit communities such as
 2 Alameda County in that they would not have to incur the foreseeable costs of
 3 the opioid epidemic gripping the country and the nation.
 4

5 422. Plaintiff is not asserting a cause of action under the CSA or other federal controlled
 6 substances laws cited above.

7 423. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
 8 and will continue to suffer economic damages including, but not limited to, significant expenses
 9 for security services, emergency, health, prosecution, corrections, and rehabilitation services, as
 10 well as the cost of opioid addiction treatment paid by Alameda County.

11 424. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered
 12 and will continue to suffer stigma damage, non-physical property damage, and damage to its
 13 proprietary interests.

14 425. Defendants' breaches of their duty of care foreseeably and proximately caused
 15 damage to Alameda County and its residents.

16 426. Manufacturer Defendants are guilty of negligence per se in that the Defendants
 17 violated applicable California laws, statutes, and regulations, in the manner in which they
 18 advertised, marketed, sold and distributed opioid products.

19 427. Distributor Defendants are guilty of negligence per se in that the Defendants violated
 20 California laws, statutes, and regulations designed to protect Plaintiff from the harms it has suffered
 21 including but not limited to the following:

- 22 a. Defendants falsely advertised opioids in violation of the Sherman Food, Drug,
 23 and Cosmetic Laws, California Health & Safety Code § 110390;
- 24 b. Defendants manufactured, sold, delivered, held, or offered for sale opioids that
 25 had been falsely advertised in violation of the Sherman Food, Drug, and
 26 Cosmetic Laws, California Health & Safety Code § 110395;

- c. Defendants received in commerce opioids that were falsely advertised or delivered or proffered for delivery opioids that were falsely advertised in violation of the Sherman Food, Drug, and Cosmetic Laws, California Health & Safety Code § 110400;
- d. Defendants failed to report all sales of dangerous drugs subject to abuse in excess of the amounts set by the California State Board of Pharmacy in violation of 16 C.C.R. §1782;
- e. Defendants failed to track and report all purchases that exceeded prior purchases by long-term care facilities or similar customers by a factor of 20 percent in violation of California Business & Professions Code § 4164; and
- f. Defendants failed to report all suspicious orders placed by California pharmacies or wholesalers after January 1, 2018 as required by California Business & Professions Code § 4169.1.

428. As a direct and proximate consequence of Defendants' negligent acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid addiction epidemic, including in Alameda County. Alameda County, as a further direct and proximate consequence and result thereof, sustained injuries and damages, including, but not limited, to tax dollars spent and costs for treatment of opioid addicted patients, emergency response costs, law and regulatory enforcement costs, and measures for prevention of further opioid abuse and addiction.

429. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and fraudulent, entitling Alameda County to punitive damages.

FOURTH CAUSE OF ACTION
(Unjust Enrichment – Against All Defendants)

430. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 429 above as if set forth fully herein.

1 431. As an expected and intended result of their conscious wrongdoing as set forth in this
2 Complaint, Defendants have profited and benefited from the increase in the distribution and
3 purchase of opioids within Alameda County, including from opioids foreseeably and deliberately
4 diverted within and into Alameda County.

5 432. Plaintiff has expended substantial amounts of money in an effort to remedy or
6 mitigate the societal harms caused by Defendants' conduct.

7 433. These expenditures include, but are not limited to, the provision of healthcare
8 services and treatment services to people who use opioids. Plaintiff has also made payments for
9 opioid addiction treatment.

10 434. These expenditures have helped sustain Defendants' businesses.

11 435. Plaintiff has conferred a benefit upon Defendants by paying for Defendants'
12 externalities: the cost of the harms caused by Defendants' improper distribution practices.

13 436. Defendants were aware of these obvious benefits, and their retention of the benefit
14 is unjust.

15 437. Plaintiff has paid for the cost of Defendants' externalities and Defendants have
16 benefited from those payments because they allowed them to continue providing customers with a
17 high volume of opioid products. Because of their deceptive marketing of prescription opioids,
18 Defendants obtained enrichment they would not otherwise have obtained. Because of their
19 conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment
20 they would not otherwise have obtained. The enrichment was without justification and Plaintiff
21 lacks a remedy provided by law.

22 438. Defendants' misconduct alleged in this case is ongoing and persistent.

23 439. Defendants have unjustly retained benefits to the detriment of Alameda County, and
24 Defendants' retention of such benefits violates the fundamental principles of justice, equity, and
25 good conscience.

26 440. Alameda County is entitled to restitution and disgorgement from Defendants in an
27 amount to be determined at trial.
28

FIFTH CAUSE OF ACTION
(Civil Conspiracy – Against All Defendants)

441. Plaintiff realleges and incorporates herein by reference each and every allegation in paragraphs 1 through 440 above as if set forth fully herein.

442. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution of opioids into California and Alameda County.

443. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing of opioids and/or distribution of opioids into California and Alameda County.

444. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

445. The Manufacturing Defendants further unlawfully coordinated in furtherance of the conspiracy by increasing the volume of opioid sales in the United States through creating a market for non-medical use of opioids of epidemic proportions.

446. Many of the Manufacturing Defendants are members, participants, and/or sponsors of the Healthcare Distribution Alliance (“HDA”), and have been since at least 2006, and utilized the HDA to give further assistance to the conspiracy.

447. The Manufacturing Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the reality of the suspicious orders that the Manufacturing Defendants were filling on a daily basis, which lead to the diversion of hundreds of millions of doses of prescription opioids into the illicit market.

448. The Manufacturing Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in a coordinated, common course of conduct to commit acts of fraud.

449. Indeed, for the Defendants’ fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics.

450. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme.

1 451. Nevertheless, in order to increase sales of their opioid products in furtherance of the
2 conspiracy, the Defendants engaged in a scheme of deception by refusing to identify or report
3 suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse,
4 and were actually being diverted into the market of non-medical use.

5 452. Defendants further unlawfully marketed opioids in California and Alameda County
6 in furtherance of that conspiracy to increase profits and sales through the knowing and intentional
7 dissemination of false and misleading information about the safety and efficacy of long-term opioid
8 use through, among other things: (a) the use of “Front Groups” that appeared to be independent of
9 the Defendants; (b) the dissemination of publications that supported the Defendants conspiracy; (c)
10 continuing medical education (“CME”) programs controlled and/or funded by the Defendants; (d)
11 hiring and deploying so-called “key opinion leaders” or “KOLs” who were paid by the Defendants
12 to promote their message; and (e) the “detailing” activities of the Defendants’ sales forces, which
13 directed deceptive marketing materials and pitches directly at physicians and, in particular, at
14 physicians lacking the expertise of pain care specialists.

15 453. Each of the Front Groups helped disguise the role of Defendants by purporting to be
16 unbiased, independent patient-advocacy and professional organizations in order to disseminate
17 patient education materials, a body of biased and unsupported scientific “literature,” and “treatment
18 guidelines” that promoted the Defendants’ false messages.

19 454. Each of the KOLs were physicians chosen and paid by each of the Defendants to
20 influence prescribers’ habits by promoting the Defendants’ false message through, among other
21 things, writing favorable journal articles and delivering supportive CMEs as if they were
22 independent medical professionals, thereby further obscuring the Defendants’ role in the
23 conspiracy.

24 455. Further, each of the Defendants, KOLs, and Front Groups had systematic links to
25 and personal relationships with each other through (a) joint participation in lobbying groups, (b)
26 trade industry organizations, (c) contractual relationships, and (d) continuing coordination of
27 activities. Specifically, each of the Defendants coordinated their efforts through the same KOLs
28 and Front Groups, based on their agreement and understanding that the Front Groups and KOLs

1 were industry-friendly and would work together with the Defendants to advance the conspiracy.

2 456. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this
3 Complaint, including, without limitation, in Plaintiff's Counts for violations California Statutes.
4 Such allegations are specifically incorporated herein.

5 457. Defendants acted with a common understanding or design to commit unlawful acts,
6 as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly and
7 proximately caused the injuries alleged herein.

8 458. Defendants acted with malice, purposely, intentionally, unlawfully, and without a
9 reasonable or lawful excuse.

10 459. Defendants conduct in furtherance of the conspiracy described herein was not mere
11 parallel conduct because each Defendant acted directly against their commercial interests in not
12 reporting the unlawful distribution practices of their competitors to the authorities, which they had
13 a legal duty to do. Each Defendant acted against their commercial interests in this regard due to an
14 actual or tacit agreement between the Defendants that they would not report each other to the
15 authorities so they could all continue engaging in their unlawful conduct.

16 460. Defendants' conspiracy, and Defendants' actions and omissions in furtherance
17 thereof, caused the direct and foreseeable losses alleged herein.

18 461. Defendants' misconduct alleged in this case is ongoing and persistent.

19 462. As a result of Defendants' conspiracy, Alameda County is entitled to compensatory
20 damages in an amount to be proved at trial.

21 463. As alleged herein, Defendants' conspiracy was willful, malicious, oppressive, and
22 fraudulent, entitling Alameda County to punitive damages.

23 **SIXTH CAUSE OF ACTION**
24 **(False Advertising – Cal. Bus. & Prof. Code § 17500 – Against All Defendants)**

25 464. Plaintiff realleges and incorporates herein by reference each and every allegation in
26 paragraphs 1 through 463 above as if set forth fully herein.

27 465. California Business & Professions Code § 17500 makes it unlawful for a business
28 to make, disseminate, or cause to be made or disseminated to the public "any statement, concerning

1 ... real or personal property ... which is untrue or misleading, and which is known, or which by the
2 exercise of reasonable care should be known, to be untrue or misleading.”

3 466. As alleged herein, the Manufacturer Defendants engaged in a systematic campaign
4 designed to disseminate false or misleading statements designed to promote the belief that opioid
5 drugs could safely be used in a non-addictive manner.

6 467. By way of example, Actavis’s predecessor created a patient brochure for Kadian in
7 2007 that deceptively stated that needing to up one’s dose to achieve the same treatment outcome
8 was not a sign of addiction. Purdue sponsored publications that expressed similar sentiments.

9 468. Actavis’s predecessor caused a patient education brochure, Managing Chronic Back
10 Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely
11 claimed that it is “less likely if you have never had an addiction problem.”

12 469. Cephalon and Purdue sponsored research and publications that falsely and
13 deceptively stated opioids did not have “ceiling dose.”

14 470. Purdue created websites, available to the public that instructed patients to seek new
15 medical providers out if their current provider would not increase their dose.

16 471. Defendants’ false and deceptive advertising practices resulted in increased opioid
17 dosages being prescribed to Alameda County’s residents, increasing the incidence of opioid
18 addiction and overdose in Alameda County.

19 472. Distributor Defendants also repeatedly omitted material information and/or falsely
20 represented that they were effectively preventing diversion and were monitoring, reporting, and
21 preventing suspicious orders.

22 473. As alleged above, Defendants’ statements about the risks associated with opioid use
23 were not supported by or were contrary to the scientific evidence.

24 474. As alleged above, each Defendant’s conduct, separately and collectively, was likely
25 to deceive California payors who purchased or covered the purchase of opioids.

26 475. Alameda County seeks restitution and injunctive relief under California Business &
27 Professions Code § 17535.

28 476. Alameda County also seeks an order assessing a civil penalty of two thousand five

1 hundred dollars (\$2,500) against Defendants for each violation of California's False Advertising
 2 Law pursuant to California Business & Professions Code § 17536.

3 **SEVENTH CAUSE OF ACTION**
 4 **(Negligent Failure to Warn— Against Manufacturer Defendants)**

5 477. Plaintiff realleges and incorporates herein by reference each and every allegation in
 6 paragraphs 1 through 476 above as if set forth fully herein.

7 478. At all relevant times, the Manufacturer Defendants had a duty to exercise reasonable
 8 and ordinary care and skill, as well as in accordance with applicable standards of conduct in
 9 adequately warning the medical profession about the risk of addiction from the use of opioid
 10 products, and not to overpromote and over-market opioid products in a manner so as to nullify,
 11 cancel out, and render meaningless any written warnings given about the risk of addiction from the
 12 use of opioid products.

13 479. Defendants breached their duty to exercise reasonable and ordinary care by failing
 14 to adequately warn the medical profession about the risk of addiction from the use of opioid
 15 products, including by overpromoting and over-marketing opioid products in a manner so as to
 16 nullify, cancel out and render meaningless any warnings in the labels about any addiction risk.
 17 Defendants' marketing, sales and promotional efforts were designed to stimulate the use of opioid
 18 products in situations and for patients who should not have been using those drugs or should have
 19 used them only as a last resort before other means were used or other less addictive and dangerous
 20 drugs were prescribed.

21 480. As a direct and proximate consequence of Defendants' negligent failure to warn,
 22 and overpromoting and over-marketing the use of prescription opioid products, there is now a
 23 national opioid addiction epidemic, including in Alameda County. The People, as a further direct
 24 and proximate consequence and result thereof, sustained injuries and damages including but not
 25 limited to tax dollars spent and costs for treatment of opioid addicted patients, emergency response
 26 costs, law and regulatory enforcement costs, opioid disposal programs, and measures for prevention
 27 of further opioid abuse and addiction.

28 481. As alleged herein, Defendants' negligence was willful, malicious, oppressive, and

1 fraudulent, entitling Alameda County to punitive damages.

2 **EIGHTH CAUSE OF ACTION**
 3 **(Fraudulent Transfer – Cal. Civ. Code § 3439.04(a)(1) – Against Sackler**
 4 **Defendants)**

4 482. Plaintiff realleges and incorporates herein by reference each and every allegation in
 5 paragraphs 1 through 481 above as if set forth fully herein.

6 483. As set forth above, Plaintiff possesses a variety of causes of action against Purdue
 7 and the other Defendants, and as soon as final judgment is entered in this action, Plaintiff will
 8 possess a right to payment from Purdue.

9 484. Plaintiff has been harmed because Plaintiff is informed and believes that Purdue has
 10 been transferring assets to the Sackler Defendants and other shareholders for years in order to avoid
 11 paying the judgment that will be owed Plaintiff, as well as the multitude of other plaintiffs that have
 12 commenced litigation against Purdue nationwide for its role in creating the opioid epidemic.

13 485. Plaintiff is informed and believes that Purdue transferred assets to the Sackler
 14 Defendants and other shareholders with the intent to hinder, delay, or defraud Purdue's creditors,
 15 including Plaintiff.

16 486. Plaintiff was harmed as a result of these transfers, and Plaintiff is entitled to void
 17 them pursuant to California Civil Code § 3439.04(a)(1).

18 **NINTH CAUSE OF ACTION**
 19 **(Civil Conspiracy – Against Purdue and Sackler Defendants)**

20 487. Plaintiff realleges and incorporates herein by reference each and every allegation in
 21 paragraphs 1 through 486 above as if set forth fully herein.

22 488. As alleged above, Purdue and the Sackler Defendants engaged in a knowing and
 23 willful conspiracy between themselves to fraudulently transfer assets from Purdue to the Sackler
 24 Defendants and other shareholders in order to hinder, delay, and defraud Plaintiff in the collection
 25 of its judgment against Purdue entered in this action.

26 489. After the Sackler Defendants became aware in or about 1999 that Purdue faced
 27 potential liability because of the addictive nature of Oxycontin, Purdue and the Sackler Defendants
 28 conspired to shield the proceeds of their wrongdoing from creditors like Plaintiff by stripping

1 Purdue every year of hundreds of millions of dollars of profits from the sale of Oxycontin and other
2 opioid-containing medications via distributions from Purdue to shareholders, including the Sackler
3 Defendants and their extended family.

4 490. Purdue and the Sackler Defendants, with knowledge and intent, agreed to the overall
5 objective of their fraudulent scheme and participated in a coordinated, common course of conduct
6 to commit acts of fraud.

7 491. Purdue and the Sackler Defendants acted with a common understanding or design
8 to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful
9 excuse, which directly and proximately caused the injuries alleged herein.

10 492. Purdue and the Sackler Defendants acted with malice, purposely, intentionally,
11 unlawfully, and without a reasonable or lawful excuse.

12 493. As a proximate result of Purdue and the Sackler Defendants' conspiracy and the
13 distributions of billions of dollars in profits to the Sackler Defendants, Plaintiff is informed and
14 believes that Purdue lacks sufficient assets to satisfy its liabilities to Plaintiff pursuant to the
15 judgment entered in this action.

16 494. As a result of Purdue and the Sackler Defendants' conspiracy, Plaintiff is entitled to
17 compensatory damages in an amount to be proved at trial.

18 495. As alleged herein, Purdue and the Sackler Defendants' conspiracy was willful,
19 malicious, oppressive, and fraudulent, entitling Plaintiff to punitive damages.

20
21 **PRAYER FOR RELIEF**

22 WHEREFORE, Alameda County and the People respectfully request judgment in their
23 favor granting the following relief:

- 24 a) Entering Judgment in favor of Alameda County and the People in a final order
25 against each of the Defendants;
- 26 b) An award of actual and consequential damages in an amount to be determined at
27 trial;
- 28 c) An order obligating Defendants to disgorge all revenues and profits derived from
their scheme;

- d) An order declaring that Defendants have made, disseminated as part of a plan or scheme, or aided and abetted the dissemination of false and misleading statements in violation of the False Advertising Law;
- e) Enjoin Defendants from performing or proposing to perform any further false or misleading statements in violation of the False Advertising Law. Any injunctive relief Plaintiff obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain in place from the Final Judgment;
- f) An order requiring Defendants to pay civil penalties for each act of false and misleading advertising, pursuant to California Business & Professions Code §§ 17500 and 17536;
- g) An order requiring Defendants to pay restitution pursuant to California Business & Professions Code § 17535;
- h) An order requiring Defendants to pay treble the amount of all relief awarded by the Court, pursuant to California Civil Code § 3345;
- i) An order declaring that Defendants have created a public nuisance in violation of California Civil Code §§ 3479 and 3480;
- j) An order enjoining Defendants from performing any further acts in violation of California Civil Code §§ 3479 and 3480;
- k) An order requiring Defendants to abate the public nuisance that they created in violation of California Civil Code §§ 3479 and 3480.
- l) An order requiring that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- m) An order requiring Defendants to fund an “abatement fund” for the purposes of abating the public nuisance;
- n) An order awarding the damages caused by the opioid epidemic, including, *inter alia*, (a) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; (e) costs associated with public safety and security services relating to the opioid epidemic; (f) costs for cleanup of public areas;
- o) An order that the transfers from Purdue to the Sackler Defendants be set aside to the extent necessary to satisfy Plaintiff’s judgment against Purdue herein;
- p) An order that an order pendente lite be granted Plaintiff enjoining and restraining the Sackler Defendants and their representatives, attorneys, servants, and agents from selling, transferring, conveying, assigning, or otherwise disposing of any of the property transferred to them by Purdue;
- q) An order that the judgment granted herein be declared a lien against the property transferred to the Sackler Defendants by Purdue;

- r) An award of punitive damages;
- s) Injunctive relief prohibiting Defendants from continuing their wrongful conduct;
- t) As award of Plaintiff's costs, including reasonable attorneys' fees, pursuant to California Code of Civil Procedure § 1021.5;
- u) Pre- and post-judgment interest as allowed by law; and
- v) Any other relief deemed just, proper, and/or equitable.

PLAINTIFF DEMAND A JURY TRIAL ON ALL CLAIMS SO TRIABLE

Dated: March 27, 2019

ROBINS KAPLAN LLP

By: 

Roman Silberfeld
Bernice Conn
Michael A. Geibelson
Lucas A. Messenger

ROBINS KAPLAN LLP
ATTORNEYS AT LAW
LOS ANGELES

EXHIBIT K

**OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA**

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ORANGE

THE PEOPLE OF THE STATE OF
CALIFORNIA, acting by and through Santa
Clara County Counsel James R. Williams,
Orange County District Attorney Tony
Rackauckas, Los Angeles County Counsel Mary
C. Wickham, and Oakland City Attorney Barbara
J. Parker,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA
INC.; THE PURDUE FREDERICK
COMPANY, INC.; TEVA
PHARMACEUTICAL INDUSTRIES, LTD;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. n/k/a JANSSEN
PHARMACEUTICALS, INC.; JANSSEN
PHARMACEUTICA, INC. n/k/a JANSSEN

No. 30-2014-00725287-CU-BT-CXC

**SIXTH AMENDED COMPLAINT FOR
VIOLATIONS OF CALIFORNIA FALSE
ADVERTISING LAW, CALIFORNIA
UNFAIR COMPETITION LAW, AND
PUBLIC NUISANCE, SEEKING CIVIL
PENALTIES, ABATEMENT, AND
INJUNCTIVE RELIEF**

Judge: Honorable Kim G. Dunning
Department: CX104

1 PHARMACEUTICALS, INC.; ENDO HEALTH
2 SOLUTIONS INC.; ENDO
3 PHARMACEUTICALS, INC.; ACTAVIS PLC;
4 ACTAVIS, INC.; WATSON,
5 PHARMACEUTICALS, INC. n/k/a ACTAVIS,
6 INC.; WATSON LABORATORIES, INC.;
7 ACTAVIS LLC; and ACTAVIS PHARMA,
8 INC. f/k/a WATSON PHARMA, INC.; AND
9 DOES 1 THROUGH 100, INCLUSIVE,
10 Defendants.

TABLE OF CONTENTS**Page**

I.	INTRODUCTION	1
II.	PARTIES	5
A.	Plaintiff	5
B.	Defendants	5
III.	JURISDICTION AND VENUE	9
IV.	FACTUAL ALLEGATIONS	9
A.	Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.	10
B.	Defendants Used Multiple Avenues To Disseminate Their False And Misleading Statements About Opioids.	11
1.	Defendants Spread and Continue to Spread Their False and Misleading Statements Through Direct Marketing of Their Branded Opioids.	11
2.	Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Misleading Statements About the Risks and Benefits of Opioids.	14
C.	Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.	17
1.	Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long-Term Opioid Use.	17
2.	Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.	29
D.	Defendants Also Engaged In Other Unlawful, Unfair, And Fraudulent Misconduct.	34
E.	Although Defendants Knew That Their Marketing Of Opioids Was False And Misleading, They Fraudulently Concealed Their Misconduct.	36
F.	By Knowingly Causing an Explosion in Opioid Prescribing Use, Misuse, Abuse, and Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair Business Practices, Each Defendant Has Created or Assisted in the Creation of a Public Nuisance.	38
1.	Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a Huge Increase in Opioid Prescriptions and Use in California, Including Santa Clara, Orange and Los Angeles Counties, and the City of Oakland.	38
2.	By Causing an Explosion in Opioid Prescriptions and Use, Defendants Have Created or Assisted in the Creation of a Public Nuisance in California, Including Santa Clara, Orange and Los Angeles Counties, and the City of Oakland.	40
3.	Defendants Knew and Should Have Known That their Deceptive Marketing Schemes Would Create or Assist in the Creation of This	

1	Public Nuisance in Santa Clara, Orange and Los Angeles Counties, and the City of Oakland.....	43
2	4. Defendants' Conduct and Role in Creating or Assisting in the	
3	Creation of this Public Nuisance is Not Excused by the Actions of	
	any Third Parties and Justifies Greater Civil Penalties	43
4	G. Defendants' Fraudulent Marketing Has Led To Record Profits.	44
5	V. CAUSES OF ACTION.....	44
6	VI. PRAYER FOR RELIEF	49

I. INTRODUCTION

1. Defendants manufacture, market, and sell prescription opioids (hereinafter opioids), including brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, opioids were used only to treat short-term acute pain or for palliative (end-of-life) care because they were considered too addictive and debilitating for the treatment of chronic pain, like back pain, migraines, and arthritis.¹

2. In the late 1990s, however, and continuing today, each Defendant began a sophisticated marketing scheme premised on deception to persuade doctors and patients that opioids can and should be used to treat chronic pain. Each Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. As to the risks, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction;² (2) promoted the concept of “pseudoaddiction,” claiming that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Defendants also falsely touted the benefits of long-term opioid use, including its supposed ability to improve function and quality of life, even though there was no “good evidence” to support those benefits.

3. Each Defendant knew that its longstanding and ongoing misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant’s misrepresentations has been confirmed by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain*, issued in

¹ In this Complaint, “chronic pain” means non-cancer pain lasting three months or longer.

² Addiction is classified as a spectrum of “substance use disorders” that range from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on this spectrum. In this Complaint, “addiction” refers to the entire range of substance abuse disorders.

1 2016 and approved by the FDA (2016 CDC Guideline). Yet even now, each Defendant continues
 2 to misrepresent the risks and benefits of long-term opioid use in California, and continues to fail to
 3 correct its past misrepresentations.

4 4. Defendants' false and misleading statements deceived doctors and patients about the
 5 risks and benefits of opioids and convinced them that opioids were not only appropriate but
 6 necessary for the treatment of chronic pain. Defendants targeted susceptible prescribers like family
 7 doctors as well as vulnerable patient populations like the elderly and veterans. And they tainted the
 8 sources that doctors and patients relied upon for guidance, including treatment guidelines,
 9 continuing medical education programs, medical conferences and seminars, and scientific articles.
 10 As a result, Defendants successfully transformed the way doctors treat chronic pain, opening the
 11 floodgates of opioid prescribing and use. Opioids are now the most prescribed class of drugs; they
 12 generated \$11 billion in revenue for drug companies in 2014 alone. This explosion in opioid
 13 prescriptions and use has padded Defendants' profit margins at the expense of chronic pain
 14 patients. As the CDC recently concluded, "for the vast majority of [those] patients, the known,
 15 serious, and too-often-fatal risks far outweigh the unproven and transient benefits."³

16 5. The explosion in opioid prescriptions and use caused by Defendants has led to a
 17 public health crisis in California. California faces skyrocketing opioid addiction and opioid-related
 18 overdoses and deaths as well as devastating social and economic consequences. This public health
 19 crisis is a public nuisance because it "is injurious to health" and interferes "with the comfortable
 20 enjoyment of life and property" (Civ. Code, § 3479) and because it affects "entire communit[ies]"
 21 and "neighborhood[s]" and "any considerable number of persons" (*id.*, § 3480). The effects of each
 22 Defendant's deceptive marketing scheme are catastrophic and are only getting worse. This is
 23 especially so in Santa Clara, Orange and Los Angeles counties, and the City of Oakland. In Orange
 24 County, for example, there were 286 overdose deaths in 2015, a 16% increase since 2013. In Los
 25 Angeles County, there were nearly 400 overdose deaths involving prescription opioids each year
 26

27 _____
 28 ³ Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).

1 from 2006 to 2013. In 2016, Oakland's age adjusted death rate from prescription opioid overdose
 2 was approximately 4.3 per 100,000 residents, higher than the state average of 3.43 deaths per
 3 100,000 residents; in some neighborhoods, deaths were as high as 10.21 per 100,000 residents. In
 4 Oakland, the opioid epidemic has disproportionately affected communities of color, and the City's
 5 African American residents experience the adverse effects of addiction and overdose at
 6 significantly higher rates.

7 6. As the FDA acknowledged in February 2016, "[t]hings are getting worse, not better,
 8 with the epidemic of opioid misuse, abuse and dependence."⁴

9 7. There is little doubt that each Defendant's deceptive marketing scheme has
 10 precipitated this public health crisis in California, including Santa Clara, Orange and Los Angeles
 11 counties, and the City of Oakland, by dramatically increasing opioid prescriptions and use. An
 12 oversupply of prescription opioids has provided a source for illicit use or sale of opioids (the
 13 supply), while the widespread use of opioids has created a population of patients physically and
 14 psychologically dependent on them (the demand). And when those patients can no longer afford or
 15 legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

16 8. The role of Defendants' deceptive marketing scheme in causing this public health
 17 crisis has become well-recognized in recent years. In her May 2014 testimony to the Senate Caucus
 18 on International Narcotics Control on behalf of the National Institutes of Health (NIH), Dr. Nora
 19 Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have
 20 contributed to the severity of the current prescription drug abuse problem."⁵ And in August 2016,
 21 the former U.S. Surgeon General expressly connected the "urgent health crisis" to "heavy
 22 marketing of opioids to doctors [m]any of [whom] were even taught – incorrectly – that
 23

24
 25 ⁴ *Califf, FDA top officials call for sweeping review of agency opioids policies*, FDA News
 26 Release (Feb. 4, 2016), available at
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm>.

27 ⁵ *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, available at
 28 <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse> [as of July 7, 2017].

1 opioids are not addictive when prescribed for legitimate pain.”⁶ California doctors, addiction
 2 treatment specialists, and law enforcement and public health officials confirm that prescription
 3 opioids lawfully prescribed by doctors have fueled this epidemic.

4 9. Absent each Defendant’s deceptive marketing scheme, opioid prescribing, use,
 5 misuse, abuse, and addiction, would not have become so widespread, and the opioid epidemic that
 6 now exists would have been averted or much less severe.

7 10. By falsely downplaying the risks and grossly exaggerating the benefits of long-term
 8 opioid use through their deceptive marketing claims despite their knowledge of the falsity of those
 9 claims, Defendants have not only engaged in false advertising and unfair competition, they have
 10 also created or assisted in the creation of a public nuisance.⁷ Although this Complaint focuses on
 11 Defendants’ misconduct during the past six years and only references their earlier misconduct,
 12 every act of malfeasance committed by each Defendant since the late 1990s as part of its deceptive
 13 marketing scheme subjects that Defendant to liability for public nuisance because there is no
 14 statute of limitations for a public nuisance claim. (See Civ. Code, § 3490 [“No lapse of time can
 15 legalize a public nuisance, amounting to an actual obstruction of public right”]; *Wade v. Campbell*
 16 (1962) 200 Cal.App.2d 54, 61 [“the maintenance of a public nuisance may not be defended on the
 17 ground of laches or the statute of limitations”].)

18 11. Accordingly, Defendants’ conduct, both individually and collectively, has violated
 19 and continues to violate the False Advertising Law, Bus. & Prof. Code, §§ 17500 et seq., the
 20 Unfair Competition Law, Bus. & Prof. Code, §§ 17200 et seq.,⁸ and the Public Nuisance Law, Civ.
 21 Code, §§ 3479 and 3480. The People of the State of California do not seek to limit the ability of
 22

23 _____
 24 ⁶ Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at
<http://turnthetidex.org/>.

25 ⁷ (See *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 306
 26 [holding that plaintiffs “have adequately alleged that defendants are liable for the abatement of this
 27 public nuisance” by alleging that defendants “promot[ed] lead paint for interior use even though
 defendants knew for nearly a century that such a use of lead paint was hazardous to human
 beings”].)

28 ⁸ The claim under Bus. & Prof. Code §§ 17200 et seq. is asserted by the People only
 through the Orange County District Attorney.

doctors in California to prescribe opioids. The People also do not ask this Court to weigh the risks and benefits of long-term opioid use. Instead, the People seek an order requiring Defendants to cease their unlawful promotion of opioids, to correct their misrepresentations, and to abate the public nuisance they have created. To redress and punish Defendants' previous and current violations of law, the People seek a judgment requiring Defendants to pay civil penalties, and any fees or costs permitted under law.

II. PARTIES

A. Plaintiff

12. James R. Williams, County Counsel for the County of Santa Clara, Tony Rackauckas, District Attorney for the County of Orange, Mary C. Wickham, County Counsel for the County of Los Angeles, and Barbara J. Parker, City Attorney for the City of Oakland bring this action on behalf of the People of the State of California (People) to protect the public from false and misleading advertising, unlawful, unfair, and fraudulent business practices, and a public nuisance.

B. Defendants

13. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, Purdue).

14. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,⁹ and Targiniq ER in the U.S. and California. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

⁹ Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.

1 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs
2 (painkillers).

3 15. In May 2007, Purdue entered into a stipulated final judgment with the People of the
4 State of California, acting by and through the California Attorney General (Purdue Final
5 Judgment), based principally on Purdue's direct promotion of OxyContin up to May 8, 2007, the
6 effective date of the Final Judgment. The People do not seek, through this Complaint, to enforce
7 any provision of the Purdue Final Judgment, and are not seeking any relief against Purdue under
8 any state consumer protection law as defined by section (I)(1)(M) and footnote 1 of the Final
9 Judgment based on any conduct by Purdue that occurred at any time up to and including May 8,
10 2007 relating to Purdue's promotional and marketing practices regarding OxyContin. The People
11 do, however, assert claims arising under California law independent of the Purdue Final Judgment,
12 and seek penalties, in addition to injunctive relief, as afforded by those laws.

13 16. CEPHALON, INC. is a Delaware corporation with its principal place of business in
14 Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (Teva Ltd.) is an Israeli
15 corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired
16 Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (Teva USA) is a wholly-owned
17 subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in
18 Pennsylvania. Teva USA acquired Cephalon in October 2011.

19 17. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq
20 and Fentora in the U.S. and California. Actiq and Fentora have been approved by the FDA only for
21 the "management of breakthrough cancer pain in patients 16 years of age and older who are already
22 receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."¹⁰ In
23 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for
24 its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.

25 18. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell
26 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for
27

28 ¹⁰ Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with
otherwise stable persistent pain.

1 Cephalon in the United States through Teva USA and has done so since its October 2011
 2 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to
 3 the public. Teva USA sells all former Cephalon branded products through its “specialty medicines”
 4 division. The FDA-approved prescribing information and medication guide, which is distributed
 5 with Cephalon opioids marketed and sold in California, discloses that the guide was submitted by
 6 Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has
 7 directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription
 8 savings cards distributed in California, indicating Teva Ltd. would be responsible for covering
 9 certain co-pay costs. All of Cephalon’s promotional websites, including those for Actiq and
 10 Fentora, prominently display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and
 11 Teva USA’s sales as its own, and its year-end report for 2012—the year immediately following the
 12 Cephalon acquisition—attributed a 22% increase in its specialty medicine sales to “the inclusion of
 13 a full year of Cephalon’s specialty sales.” Through interrelated operations like these, Teva Ltd.
 14 operates in California and the rest of the United States through its subsidiaries Cephalon and Teva
 15 USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global
 16 revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd.
 17 would conduct those companies’ business in the United States itself. Upon information and belief,
 18 Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the
 19 benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva
 20 Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as “Cephalon.”)

21 19. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its
 22 principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of
 23 JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in
 24 New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now
 25 known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of
 26 business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as Janssen
 27 Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in
 28 Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen

1 Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon
2 information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs
3 and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen
4 Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.").

5 20. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and
6 California, including the opioid Duragesic. Before 2009, Duragesic accounted for at least \$1 billion
7 in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta
8 and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

9 21. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal
10 place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-
11 owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal
12 place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals
13 Inc. are referred to as "Endo.")

14 22. Endo develops, markets, and sells prescription drugs, including the opioids
15 Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and California. Opioids made up
16 roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15
17 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012.
18 Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone,
19 hydromorphone, and hydrocodone products in the U.S. and California, by itself and through its
20 subsidiary, Qualitest Pharmaceuticals, Inc.

21 23. ALLERGAN PLC is a public limited company incorporated in Ireland with its
22 principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March
23 2015, and the combined company changed its name to Allergan plc in January 2013. Before that,
24 WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the
25 combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in
26 October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place
27 of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis,
28 Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a

1 Delaware corporation with its principal place of business in New Jersey, and was formerly known
2 as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its
3 principal place of business in Parsippany, New Jersey. Each of these defendants is owned by
4 Allergan plc, which uses them to market and sell its drugs in the United States. Upon information
5 and belief, Allergan plc exercises control over these marketing and sales efforts and profits from
6 the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc,
7 Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma,
8 Inc., and Watson Laboratories, Inc. are referred to as “Actavis.”)

9 24. Actavis manufactures, promotes, sells, and distributes opioids, including the
10 branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic
11 and Opana, in the U.S. and California. Actavis acquired the rights to Kadian from King
12 Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

13 25. Plaintiff is ignorant of the true names or capacities, whether individual, corporate or
14 otherwise, of the Defendants sued herein under the fictitious names DOES 1 through 100 inclusive,
15 and they are therefore sued herein pursuant to Code of Civil Procedure § 474. Plaintiff will amend
16 this Complaint to show their true names and capacities if and when they are ascertained. Plaintiff is
17 informed and believes, and on such information and belief alleges, that each of the Defendants
18 named as a DOE is responsible in some manner for the events and occurrences alleged in this
19 Complaint and is liable for the relief sought herein.

20 **III. JURISDICTION AND VENUE**

21 26. This Court has jurisdiction over this action. Defendants are engaging in false and
22 misleading advertising and unlawful, unfair, and deceptive business practices, and creating or
23 assisting in the creation of a public nuisance in Santa Clara, Orange and Los Angeles counties, and
24 the City of Oakland, and the County Counsel, the District Attorney, and the City Attorney have the
25 right and authority to prosecute this case on behalf of the People.

26 27. Venue is proper in this Court because Defendants transact business in Orange
27 County, and some of the acts complained of occurred in this venue.

IV. FACTUAL ALLEGATIONS

28. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

29. To take advantage of the much larger and more lucrative market for chronic pain patients, Defendants had to change this. Each Defendant developed a well-funded marketing scheme based on deception. Each Defendant targeted susceptible prescribers and vulnerable patient populations. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and misleading statements about the risks and benefits of long-term opioid use. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence. California doctors, including doctors in Santa Clara County, confirm that Defendants began their marketing schemes decades ago and continue them today. And the 2016 CDC Guideline makes it patently clear that their schemes were and continue to be deceptive.

A. Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.

30. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including California.

31. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be schooled in treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations. Interviews with California doctors, including

1 doctors in Santa Clara County, confirm that Defendants' deceptive marketing scheme has long
2 targeted and continues to target primary care doctors in California.

3 32. Defendants also targeted vulnerable patient populations like the elderly and
4 veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even
5 though the risks of long-term opioid use were significantly greater for them. For example, the 2016
6 CDC Guideline observed that existing evidence showed that elderly patients taking opioids suffer
7 from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to
8 adverse drug effects and interactions. The Guideline therefore concluded that there are "special
9 risks of long-term opioid use for elderly patients" and recommended that doctors use "additional
10 caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same
11 is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-
12 traumatic stress disorder, which interact dangerously with opioids.

13 **B. Defendants Used Multiple Avenues To Disseminate Their False And Misleading**
14 **Statements About Opioids.**

15 33. To spread their false and misleading statements, Defendants deceptively marketed
16 their branded opioids directly to doctors and patients in California. Defendants also deployed
17 seemingly unbiased and independent third parties to spread their false and misleading statements
18 about the risks and benefits of opioids for the treatment of chronic pain throughout California.

19 1. Defendants Spread and Continue to Spread Their False and Misleading Statements
20 Through Direct Marketing of Their Branded Opioids.

21 34. Defendants' direct marketing of opioids generally proceeded on two tracks. First,
22 each Defendant conducted and continues to conduct advertising campaigns touting the purported
23 benefits of their branded drugs. For example, Defendants spent more than \$14 million on medical
24 journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included
25 \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

26 35. A number of Defendants' branded ads deceptively portrayed the benefits of opioids
27 for chronic pain. For example, since at least May 21, 2011, Endo has distributed and made
28 available on its website opana.com a pamphlet promoting Opana ER with photographs depicting

1 patients with physically demanding jobs like construction worker and chef, misleadingly implying
2 that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a
3 series of ads, called “Pain vignettes,” for OxyContin in 2012 in medical journals. These ads
4 featured chronic pain patients and recommended OxyContin for each. One ad described a “54-year-
5 old writer with osteoarthritis of the hands” and implied that OxyContin would help the writer work
6 more effectively.

7 36. Second, each Defendant promoted the use of opioids for chronic pain through
8 “detailers” – sales representatives who visited individual doctors and medical staff in their offices –
9 and small group speaker programs. For example, from mid-2013 through 2015, Purdue, Janssen,
10 and Endo detailed at least 6,238, 584, and 195 prescribers in California respectively. Purdue itself
11 was responsible for more than 1 out of every 3 reported opioid-related detailing visits in California
12 by Defendants.

13 37. As doctors in California, including doctors in Santa Clara and Orange County,
14 interviewed by the People have confirmed, these detailers have spread and continue to spread
15 misinformation regarding the risks and benefits of opioids to hundreds of thousands of doctors,
16 including thousands of California doctors. For example, these doctors have confirmed that
17 Defendants’ detailers, over the past two years, continue to falsely and misleadingly:

- 18 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 19 b. Describe their opioid products as “steady state” – falsely implying that these
20 products are less likely to produce the high and lows that fuel addiction – or
21 as less likely to be abused or result in addiction;
- 22 c. Tout the effectiveness of screening or monitoring patients as a strategy for
23 managing opioid abuse and addiction;
- 24 d. State that there is no maximum dose and that doctors can safely increase
25 doses without disclosing the significant risks to patients at higher doses;
- 26 e. Discuss “pseudoaddiction”;
- 27 f. State that patients would not experience withdrawal if they stopped using
28 their opioid products;

- 1 g. State that their opioid products are effective for chronic pain without
2 disclosing the lack of evidence for the effectiveness of long-term opioid use;
3 and
4 h. State that abuse-deterrent formulations are tamper- or crush-resistant and
5 harder to abuse or misuse.

6
7 38. Because these detailers must adhere to scripts and talking points drafted by
8 Defendants, it can be reasonably inferred that most, if not all, of Defendants' detailers made and
9 continue to make these misrepresentations to the thousands of California doctors they have visited
10 and continue to visit. Defendants have not corrected this misinformation.

11 39. Defendants¹¹ also identified doctors to serve, for payment, on their speakers'
12 bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker
13 programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be
14 selected to promote the drug); (2) recognition and compensation for the doctors selected as
15 speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These
16 speakers give the false impression that they are providing unbiased and medically accurate
17 presentations when they are, in fact, presenting a script prepared by Defendants. On information
18 and belief, these presentations conveyed misleading information, omitted material information, and
19 failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

20 40. Each Defendant devoted and continues to devote massive resources to direct sales
21 contacts with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded opioids
22 to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount
23 includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$10
24 million by Endo, and \$2 million by Actavis.

25
26
27

¹¹ Upon information and belief, Actavis continued to carry out speaker programs after it
28 acquired Kadian.

41. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Moreover, more frequent prescribers of opioids in California are generally more likely to have received a detailing visit. And in some instances, more infrequent prescribers of opioids in California received a detailing visit from a Defendant's detailer and then prescribed only that Defendant's opioid products.

42. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Misleading Statements About the Risks and Benefits of Opioids.

43. Defendants also deceptively marketed opioids in California through unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain.¹²

44. Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal

¹² The phrase "acted in concert" includes conspiring to achieve some end and aiding and abetting in the commission of acts necessary to achieve some end.

1 their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use
2 for chronic pain.

3 45. Defendants' deceptive unbranded marketing often contradicted what they said in
4 their branded materials reviewed by the FDA. For example, Endo's unbranded advertising
5 contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
"People who take opioids as prescribed usually do not become addicted."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

13 46. Defendants also spoke through a small circle of doctors who, upon information and
14 belief, were selected, funded, and elevated by Defendants because their public positions supported
15 the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or
16 "KOLs." Defendants paid these KOLs to serve as consultants or on their advisory boards and to
17 give talks or present continuing medical education programs (CMEs), and their support helped
18 these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the
19 benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals.
20 KOLs' professional reputations became dependent on continuing to promote a pro-opioid message,
21 even in activities that were not directly funded by Defendants.

22 47. Pro-opioid doctors are one of the most important avenues that Defendants use to
23 spread their false and misleading statements about the risks and benefits of long-term opioid use.
24 Defendants know that doctors rely heavily and more uncritically on their peers for guidance, and
25 KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For
26 example, the New York Attorney General (NY AG) found in its settlement with Purdue that
27 through March 2015 the Purdue website *In the Face of Pain* failed to disclose that doctors who
28

1 provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to
2 disclose these financial connections potentially misled consumers regarding the objectivity of the
3 testimonials. KOLs have written, consulted on, edited, and lent their names to books and articles,
4 and given speeches and CMEs supportive of chronic opioid therapy. Defendants created
5 opportunities for KOLs to participate in research studies Defendants suggested or chose and then
6 cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not
7 support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic
8 opioid therapy.

9 48. Defendants' KOLs also served on committees that developed treatment guidelines
10 that strongly encourage the use of opioids to treat chronic pain and on the boards of pro-opioid
11 advocacy groups and professional societies that develop, select, and present CMEs. These
12 guidelines and CMEs were not supported by the scientific evidence at the time they were created,
13 and they are not supported by the scientific evidence today. Defendants were able to direct and
14 exert control over each of these activities through their KOLs. The 2016 CDC Guideline
15 recognizes that treatment guidelines can "change prescribing practices."

16 49. Defendants also entered into arrangements with seemingly unbiased and
17 independent patient and professional organizations to promote opioids for the treatment of chronic
18 pain. Under the direction and control of Defendants, these "Front Groups" – which include, but are
19 not limited to, the American Pain Foundation (APF) and the American Academy of Pain Medicine
20 – generated treatment guidelines, unbranded materials, and programs that favored chronic opioid
21 therapy. These guidelines, materials, and programs were not supported by the evidence at the time
22 they were created, and they are not supported by the scientific evidence today. Indeed, they stand
23 in marked contrast to the 2016 CDC Guideline. These Front Groups also assisted Defendants by
24 responding to negative articles, by advocating against regulatory changes that would limit opioid
25 prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable
26 patient populations targeted by Defendants.

27 50. These Front Groups depended on Defendants for funding and, in some cases, for
28 survival. Defendants also exercised control over programs and materials created by these groups by

1 collaborating on, editing, and approving their content, and by funding their dissemination. For
2 example, Purdue's consulting agreement with APF gave it direct, contractual control over APF's
3 work. In doing so, Defendants made sure that the Groups would generate only the messages
4 Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent
5 and serving the needs of their members – whether patients suffering from pain or doctors treating
6 those patients.

7 51. Defendants worked together, through Front Groups, to spread their deceptive
8 messages about the risks and benefits of long-term opioid therapy. For example, Defendants
9 combined their efforts through the Pain Care Forum (PCF), which began in 2004 as an APF
10 project. PCF is comprised of representatives from opioid manufacturers (including Cephalon,
11 Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial
12 funding from Defendants. Among other projects, PCF worked to ensure that an FDA-mandated
13 education project on opioids was not unacceptably negative and did not require mandatory
14 participation by prescribers, which Defendants determined would reduce prescribing. PCF also
15 worked to address a perceived “lack of coordination” among its members and developed “key”
16 messages that were disseminated in programs and industry-run websites that were available and
17 accessible after May 21, 2011.

18 **C. Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.**

19 52. To convince doctors and patients in California that opioids can and should be used
20 to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and
21 helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks
22 and benefits of long-term opioid use, Defendants made claims that were not supported by or were
23 contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA
24 and the CDC based on that evidence confirm that their claims were false and misleading,
25 Defendants have not corrected them and continue to spread them today.

26 1. Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long-
27 Term Opioid Use.

53. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

54. **First**, Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and misleading claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." This website was still available online after May 21, 2011.
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

1 A similar statement appeared on the Endo website www.opana.com – which was
2 accessible online after May 21, 2011.

- 3 e. Janssen reviewed, edited, approved, and distributed a patient education guide
4 entitled *Finding Relief: Pain Management for Older Adults* (2009), which
5 described as “myth” the claim that opioids are addictive, and asserted as fact that
6 “[m]any studies show that opioids are *rarely* addictive when used properly for
7 the management of chronic pain.” This guide is still available online.
- 8 f. Janssen currently runs a website, *Prescriberesponsibly.com* (last updated July 2,
9 2015), which claims that concerns about opioid addiction are “overestimated.”
- 10 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its*
11 *Management* – which claims that less than 1% of children prescribed opioids
12 will become addicted and that pain is undertreated due to “misconceptions about
13 opioid addiction[.]” This publication is still available online.
- 14 h. Since at least May 21, 2011, detailers for Purdue, Endo, Janssen, and Cephalon
15 in California have minimized or omitted and continue to minimize or omit any
16 discussion with doctors or their medical staff in California, including Santa
17 Clara County, about the risk of addiction; misrepresented the potential for abuse
18 of opioids with purportedly abuse-deterrent formulations; and routinely did not
19 correct the misrepresentations noted above.

20 55. These claims are contrary to longstanding scientific evidence, as the FDA and CDC
21 have conclusively declared. As noted in the 2016 CDC Guideline approved by the FDA, there is
22 “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an
23 alternative term for opioid addiction]).” The Guideline points out that “[o]pioid pain medication
24 use presents serious risks, including . . . opioid use disorder” and that “continuing opioid therapy
25 for 3 months substantially increases risk for opioid use disorder.” (Emphasis added.)

26 56. The FDA further exposed the falsity of Defendants’ claims about the low risk of
27 addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in
28 2016. In its announcements, the FDA found that “most opioid drugs have ‘high potential for
abuse” and that opioids “are associated with a substantial risk of misuse, abuse, NOWS [neonatal
opioid withdrawal syndrome], addiction, overdose, and death.” (Emphasis added.) According to the
FDA, because of the “known serious risks” associated with long-term opioid use, including “risks
of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of
overdose and death,” opioids should be used only “in patients for whom alternative treatment
options” like non-opioid drugs have failed. (Emphasis added.) The FDA further acknowledged that

1 the risk is not limited to patients who seek drugs illicitly; addiction “can occur in patients
2 appropriately prescribed [opioids].”

3 57. Thus, the warnings on Defendants’ own FDA-approved drug labels caution that
4 opioids “expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and
5 death,” that the drugs contain “a substance with a high potential for abuse,” and that addiction “can
6 occur in patients appropriately prescribed” opioids. (Emphasis added.)

7 58. **Second**, Defendants falsely instructed doctors and patients that the signs of
8 addiction are actually signs of undertreated pain and should be treated by prescribing more opioids.
9 Defendants called this phenomenon “pseudoaddiction” – a term coined by Dr. David Haddox, who
10 went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo,
11 Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific
12 evidence. Some illustrative examples of these deceptive claims that were made by, are continuing
13 to be made by, and/or have not been corrected by Defendants after May 21, 2011 – are described
14 below:

- 15 a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which
16 taught that behaviors such as “requesting drugs by name”, “demanding or
17 manipulative behavior,” seeing more than one doctor to obtain opioids, and
18 hoarding, are all signs of pseudoaddiction, rather than true addiction.
19 *Responsible Opioid Prescribing* remains for sale online. Endo also distributed
20 this document before and after May 21, 2011.
- 21 b. Janssen sponsored, funded, and edited the *Let’s Talk Pain* website, which in
22 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur
23 when *pain is under-treated* Pseudoaddiction is different from true addiction
24 because such behaviors can be resolved with effective pain management.” This
25 website was accessible online until May 2012.
- 26 c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in
27 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing*
28 *Analgesia*, which promoted pseudoaddiction by teaching that a patient’s aberrant
behavior was the result of untreated pain. Endo substantially controlled NIPC by
funding NIPC projects; developing, specifying, and reviewing content; and
distributing NIPC materials. This CME program was still available after May
21, 2011.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
Abuse, which described pseudoaddiction as a concept that “emerged in the
literature” to describe the inaccurate interpretation of [drug-seeking behaviors]
in patients who have pain that has not been effectively treated.” This pamphlet
was still distributed after May 21, 2011.

- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse* in 2011. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid. This CME program was still available after May 21, 2011.
- f. Before and after May 21, 2011, detailers for Purdue have directed doctors and their medical staffs in California, including Santa Clara County, to PartnersAgainstPain.com, which contained false and misleading materials describing pseudoaddiction.
- g. Purdue sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which states: “Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated* ... Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated.” (emphasis added.) This publication is still available online.

59. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids” because the patient is “not receiving a clear benefit.”

60. **Third**, Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants’ misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after March 21, 2011 are described below:

- a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speakers bureau in 2010. The

supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.

- b. Purdue sponsored a November 2011 webinar, *Managing Patient’s Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent “overuse of prescriptions” and “overdose deaths.”
- c. As recently as 2015, Purdue has represented in scientific conferences that “bad apple” patients – and not opioids – are the source of the addiction crisis and that once those “bad apples” are identified, doctors can safely prescribe opioids without causing addiction.
- d. Since at least May 21, 2011, detailers for Purdue have touted and continue to tout to doctors in California, including Santa Clara County, the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

61. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – “for improving outcomes related to overdose, addiction, abuse, or misuse.” As a result, the Guideline recognizes that available risk screening tools “show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.” (Emphasis added.)

62. **Fourth**, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use. For example, a 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that

1 might occur. This publication was available on APF’s website until the organization dissolved in
2 May 2012. And detailers for Janssen, since at least May 21, 2011, have told and continue to tell
3 doctors in California, including Santa Clara County, that their patients would not experience
4 withdrawal if they stopped using opioids. Defendants deceptively minimized the significant
5 symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug
6 craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia
7 (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the
8 unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of
9 tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the
10 duration of opioid use and the dosage of opioids prescribed should be “limit[ed]” to “minimize the
11 need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,” because
12 “physical dependence on opioids is an expected physiologic response in patients exposed to
13 opioids for more than a few days.” (Emphasis added.) The Guideline further states that “tapering
14 opioids can be especially challenging after years on high dosages because of physical and
15 psychological dependence” and highlights the difficulties, including the need to carefully identify
16 “a taper slow enough to minimize symptoms and signs of opioid withdrawal” and to “pause[] and
17 restart[]” tapers depending on the patient’s response. The CDC also acknowledges the lack of any
18 “high-quality studies comparing the effectiveness of different tapering protocols for use when
19 opioid dosage is reduced or opioids are discontinued.”

20 63. Numerous California patients struggling with opioid addiction, including patients in
21 Santa Clara County, have described how difficult it is to stop taking prescription opioids due to the
22 extreme withdrawal symptoms. For example, one lawyer who was prescribed opioids for chronic
23 pain was told that she could easily taper off the drugs. After she became addicted, she attempted to
24 stop taking opioids. But she became so sick from withdrawal that she began buying opioids
25 illicitly. Indeed, she even considered using heroin to get through her withdrawal symptoms despite
26 her fear and aversion to injecting an illegal drug. Ultimately, the costs of prescription opioids drove
27 her to seek treatment for her addiction.

64. **Fifth**, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims that were made by, are continuing to be made by, and/or have not been corrected by Defendants after May 21, 2011 are described below:

- a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.¹³ This guide is still available for sale online.
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain." The website was still accessible online after May 21, 2011.
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

¹³ Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter nonsteroidal anti-inflammatories (or NSAIDs). Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (See e.g., *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

- f. Through March 2015, Purdue's *In the Face of Pain* website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.
- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.
- j. Since at least May 21, 2011, Purdue's detailers have told doctors in California, including Santa Clara County, that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

65. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

66. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality." In fact, a recent study found that 92% of persons who died from an opioid-related overdose were initially prescribed opioids for chronic pain

67. **Finally**, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

68. These abuse deterrent formulations (AD opioids) are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids are not “impossible to abuse.”¹⁴ They can be defeated – often quickly and easily – by those determined to do so. Moreover, they do not stop oral intake, the most common avenue for opioid misuse and abuse, and do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long-term as prescribed or who escalate their use by taking more pills or higher doses.

69. Because of these significant limitations on AD opioids and because of the heightened risk for misconceptions and for the false belief that AD opioids can be prescribed safely, the FDA has cautioned that “[a]ny communications from the sponsor companies regarding AD properties must be truthful and not misleading (based on a product’s labeling), and supported by sound science taking into consideration the totality of the data for the particular drug. Claims for AD opioid products that are false, misleading, and/or insufficiently proven do not serve the public health.”¹⁵

70. Despite this admonition, Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

71. For example, Endo has marketed Opana ER as tamper- or crush-resistant and less prone to misuse and abuse since at least May 21, 2011 even though: (1) the FDA rejected Endo’s petition to approve Opana ER as abuse-deterrent in 2012; (2) the FDA warned in a 2013 letter that there was no evidence that Opana ER “would provide a reduction in oral, intranasal or intravenous abuse”; and (3) Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Endo’s advertisements for the 2012 reformulation of Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to

¹⁴ FDA Facts: Abuse-Deterrent Opioid Medications, available at <<https://www.fda.gov/newsevents/newsroom/factsheets/lucm514939.htm>> [as of July 7, 2017].

¹⁵ *Ibid.*

1 abuse. And since 2012, detailers for Endo have informed California doctors, including doctors in
 2 Santa Clara County, that Opana ER is harder to abuse, and nurse practitioners have reported
 3 receiving tamper- and crush-resistant messages regarding Opana ER and demonstrations of Opana
 4 ER's purported abuse deterrent properties.

5 72. Because Opana ER could be "readily prepared for injection" and was linked to
 6 outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee
 7 recommended that Opana ER be withdrawn from the market. The FDA adopted this
 8 recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market.¹⁶

9 73. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its
 10 AD opioids – i.e., reformulated Oxycontin and Hysingla – since at least May 21, 2011. Before
 11 April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However,
 12 numerous California prescribers report that, beginning in 2013 and continuing today, detailers from
 13 Purdue regularly use the so-called abuse deterrent properties of Purdue's opioid products as a
 14 primary selling point to differentiate those products from their competitors. Specifically, these
 15 detailers: (1) claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted;
 16 (2) claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less
 17 likely to yield a euphoric high, and are disfavored by opioid abusers; (3) Purdue's AD opioids are
 18 "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral
 19 abuse or misuse and that its abuse deterrent properties can be defeated.

20 74. These statements and omissions by Purdue are false and misleading and conflict
 21 with or are inconsistent with the FDA-approved label for Purdue's AD opioids – which indicates
 22 that abusers do seek them because of their high likability when snorted, that their abuse deterrent
 23 properties can be defeated, and that they can be abused orally notwithstanding their abuse deterrent
 24 properties and which does not indicate that AD opioids prevent or reduce abuse, misuse, or
 25 diversion.

26
 27
 28 ¹⁶ Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017,
 available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>

75. To the contrary, testimony in litigation against Purdue and other evidence indicates that Purdue knew and should have known that “reformulated OxyContin is not better at tamper resistance than the original OxyContin” and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which the tablet has been dissolved. Even Purdue’s own website describes a study it conducted that found continued abuse of OxyContin with so-called abuse deterrent properties. Finally, there are no studies indicating that Purdue’s AD opioids are safer than any other opioid products.

76. A 2015 study also shows that many opioid addicts are abusing Purdue’s AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, *one-third* of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue’s AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.¹⁷ Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue’s AD opioids are being abused in large numbers.

77. Similarly, the 2016 CDC Guideline states that “[n]o studies” support the notion that “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,” noting that the technologies “do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes.” Tom Frieden, the Director of the CDC, has further reported that his staff could not find “any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death.”¹⁸

78. These false and misleading claims about the abuse deterrent properties of their opioids are especially troubling. First, Defendants are using these claims in a spurious attempt to

¹⁷ Cicero, Theodore J., and Matthew S. Ellis, “Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin” (2015) 72.5 *JAMA Psychiatry* 424-430.

¹⁸ Perrone, *Drugmakers push profitable, but unproven, opioid solution*, 12/15/16.

1 rehabilitate their image as responsible opioid manufacturers. Indeed, several California prescribers
 2 have reported that Purdue has conveyed that its sale of AD opioids is “atonement” for its earlier
 3 sins even though its true motive was to preserve the profits it would have lost when its patent for
 4 OxyContin expired. Indeed, Purdue introduced its first AD opioid days before that patent would
 5 have expired and petitioned the FDA to withdraw its non-AD opioid as unsafe and; thereby,
 6 prevent generic competition. Second, these claims are falsely assuaging doctors’ concerns about
 7 the toll caused by the explosion in opioid prescriptions and use and encouraging doctors to
 8 prescribe AD opioids under the mistaken belief that these opioids are safer, even though they are
 9 not. Finally, these claims are causing doctors to prescribe more AD opioids -- which are far more
 10 expensive than other opioid products even though they provide little or no additional benefit.

11 79. These numerous, longstanding misrepresentations of the risks of long-term opioid
 12 use spread by Defendants successfully convinced doctors and patients to discount those risks.

13 2. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

14 80. To convince doctors and patients that opioids should be used to treat chronic pain,
 15 Defendants also had to persuade them that there was a significant upside to long-term opioid use.
 16 But as the 2016 CDC Guideline makes clear, there is “insufficient evidence to determine the long-
 17 term benefits of opioid therapy for chronic pain.” (Emphasis added.) In fact, the CDC found that
 18 “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
 19 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
 20 randomized trials \leq 6 weeks in duration)” and that other treatments were more or equally beneficial
 21 and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to
 22 support long-term opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-
 23 controlled studies of opioids use longer than 12 weeks.” Despite this, Defendants falsely and
 24 misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested
 25 that these benefits were supported by scientific evidence. Not only have Defendants failed to
 26 correct these false and misleading claims, they continue to make them today.

27 81. For example, Defendants falsely claimed that long-term opioid use improved
 28 patients’ function and quality of life. Some illustrative examples of these deceptive claims that

1 were made by, are continuing to be made by, and/or have not been corrected by Defendants after
 2 May 21, 2011 are described below:

- 3 a. Actavis distributed an advertisement that claimed that the use of Kadian to treat
 4 chronic pain would allow patients to return to work, relieve “stress on your body
 and your mental health,” and help patients enjoy their lives.
- 5 b. Endo distributed advertisements that claimed that the use of Opana ER for
 6 chronic pain would allow patients to perform demanding tasks like construction
 work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
 7 These advertisements continued to be distributed after May 21, 2011.
- 8 c. Janssen sponsored and edited a patient education guide entitled *Finding Relief:
 9 Pain Management for Older Adults* (2009) – which states as “a fact” that
 “opioids may make it *easier* for people to live normally.” The guide lists
 10 expected functional improvements from opioid use, including sleeping through
 the night, returning to work, recreation, sex, walking, and climbing stairs and
 11 states that “[u]sed properly, opioid medications can make it possible for people
 with chronic pain to ‘return to normal.’” This guide was still available after May
 21, 2011.
- 12 d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals
 13 entitled “Pain vignettes,” which were case studies featuring patients with pain
 conditions persisting over several months and recommending OxyContin for
 14 them. The ads implied that OxyContin improves patients’ function.
- 15 e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon,
 Endo and Purdue, taught that relief of pain by opioids, by itself, improved
 16 patients’ function. The book remains for sale online.
- 17 f. Cephalon and Purdue sponsored APF’s *Treatment Options: A Guide for People
 18 Living with Pain* (2007), which counseled patients that opioids “give [pain
 patients] a quality of life we deserve.” The guide was available online until APF
 shut its doors in May 2012.
- 19 g. Endo’s NIPC website *painknowledge.com* claimed in 2009 that with opioids,
 20 “your level of function should improve; you may find you are now able to
 participate in activities of daily living, such as work and hobbies, that you were
 21 not able to enjoy when your pain was worse.” Elsewhere, the website touted
 improved quality of life (as well as “improved function”) as benefits of opioid
 22 therapy. The grant request that Endo approved for this project specifically
 indicated NIPC’s intent to make misleading claims about function, and Endo
 23 closely tracked visits to the site. This website was still accessible online after
 May 21, 2011.
- 24 h. Endo was the sole sponsor, through NIPC, of a series of non-credit educational
 25 programs titled *Persistent Pain in the Older Patient*, which claimed that chronic
 opioid therapy has been “shown to reduce pain and improve depressive
 26 symptoms and cognitive functioning.” The CME was disseminated via webcast.
- 27 i. Janssen sponsored, funded, and edited a website, *Let’s Talk Pain*, in 2009,
 28 which featured an interview edited by Janssen claiming that opioids allowed a
 patient to “continue to function.” This video is still available today on YouTube.

- j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The *Policymaker's Guide* was originally published in 2011 and is still available online today.
- k. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER, Purdue's Vice President of Health Policy, J. David Haddox, talked about the importance of opioids, including Purdue's opioids, to chronic pain patients' "quality of life," and complained that CDC statistics do not take into account that patients could be driven to suicide without pain relief.
- l. Since at least May 21, 2011, Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey to prescribers in California, including Santa Clara County, the message that opioids will improve patient function.

82. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

83. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence),

1 drugs that can kill patients or commit them to a life of addiction or recovery do not improve their
2 function and quality of life.

3 84. The 2016 CDC Guideline was not the first time a federal agency repudiated
4 Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned
5 Actavis, in response to its advertising described in paragraph 67, that "[w]e are not aware of
6 substantial evidence or substantial clinical experience demonstrating that the magnitude of the
7 effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects
8 patients may experience ... results in any overall positive impact on a patient's work, physical and
9 mental functioning, daily activities, or enjoyment of life."¹⁹ And in 2008, the FDA sent a warning
10 letter to an opioid manufacturer, making it publicly made clear "that [the claim that] patients who
11 are treated with the drug experience an improvement in their overall function, social function, and
12 ability to perform daily activities . . . has not been demonstrated by substantial evidence or
13 substantial clinical experience."

14 85. Defendants also falsely and misleadingly emphasized or exaggerated the risks of
15 competing products like NSAIDs, so that doctors and patients would look to opioids first for the
16 treatment of chronic pain. For example, Defendants, before and after May 21, 2011, have
17 overstated the number of deaths from NSAIDs and have prominently featured the risks of
18 NSAIDs, while minimizing or failing to mention the serious risks of opioids. Once again, these
19 misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and
20 CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in
21 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for
22 which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC
23 Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain,
24 particularly arthritis and lower back pain.

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26
27 ¹⁹ Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns,
28 to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at
[http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyF
DA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259240.htm).

1 86. In addition, since at least May 21, 2011, Purdue has misleadingly promoted
2 OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one
3 dose. Indeed, Purdue's detailers have, within the last two years, told a doctor in Santa Clara County
4 that OxyContin lasts 12 hours.

5 87. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all
6 times relevant to this action. According to Purdue's own research, OxyContin wears off in under
7 six hours in one quarter of patients and in under 10 hours in more than half. This is because
8 OxyContin tablets release approximately 40% of their active medicine immediately, after which
9 release tapers. This triggers a powerful initial response, but provides little or no pain relief at the
10 end of the dosing period, when less medicine is released. This phenomenon is known as "end of
11 dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients
12 taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false
13 and misleading, it also makes OxyContin more dangerous because the declining pain relief patients
14 experience toward the end of each dosing period drives them to take more OxyContin before the
15 next dosing period begins, quickly increasing the amount of drug they are taking and spurring
16 growing dependence.

17 88. Purdue's competitors were aware of this problem. For example, Endo ran
18 advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely
19 promoted OxyContin as if it were effective for a full 12 hours since at least May 21, 2011. Indeed,
20 at Purdue's instruction, Purdue's sales representatives continue to tell California doctors that
21 OxyContin lasts a full 12 hours. And if a doctor suggests that OxyContin does not last 12 hours,
22 these sales representatives, at Purdue's instruction, recommend increasing the dose, rather than the
23 frequency of use. Purdue gave its sales representatives these instructions to prevent doctors from
24 switching to a different drug and to address the unwillingness of insurers to pay for more frequent
25 use of OxyContin.

D. Defendants Also Engaged In Other Unlawful and Unfair Misconduct.

89. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

90. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.
- Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to

1 Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three
2 publications that are sent to thousands of anesthesiologists and other medical
3 professionals. The Special Report openly promotes Fentora for “multiple causes of
4 pain” – and not just cancer pain.

5 91. Cephalon’s deceptive marketing gave doctors and patients the false impression that
6 Actiq and Fentora were not only safe and effective for treating chronic pain, but were also
7 approved by the FDA for such uses.

8 92. Since at least May 21, 2010, Purdue’s sales representatives have pressed doctors to
9 prescribe its opioids in order to be rewarded with talks paid by Purdue. One California doctor
10 reported that a Purdue sales representative told her that she would no longer be asked to give paid
11 talks unless she increased her prescribing of Purdue’s drugs. Another doctor confirmed that, while
12 on Purdue’s speakers’ bureau, he did not get asked to give many paid talks because he did not
13 commonly prescribe Butrans, and doctors do not “get talks” if they do not prescribe the drug.

14 93. Although the U.S. Drug Enforcement Agency (DEA) has repeatedly informed
15 Purdue about its legal “obligation to design and operate a system to disclose . . . suspicious orders
16 of controlled substances” and to inform the DEA “of suspicious orders when discovered,” Purdue
17 also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs
18 after May 21, 2010, despite knowing about it for years. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. §
19 823(e).)

20 94. For over a decade, Purdue has been able to track the distribution and prescribing of
21 its opioids down to the retail and prescriber levels. Through its extensive network of sales
22 representatives, Purdue had and continues to have knowledge of the prescribing practices of
23 thousands of doctors in California and could identify California doctors who displayed red flags for
24 diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous
25 out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this
26 information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately
27 prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement
28 authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to

demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue’s senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue’s district manager described internally as “an organized drug ring.” In doing so, Purdue protected its own profits at the expense of public health and safety.

95. This misconduct by Purdue is ongoing. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015, Purdue’s sales representatives, at various times, failed to timely report suspicious prescribing and continued to detail those prescribers even after they were placed on a “no-call” list.

96. As Dr. Mitchell Katz, prior director of the Los Angeles County Department of Health Services, said in a *Los Angeles Times* article, “Any drug company that has information about physicians potentially engaged in illegal prescribing or prescribing that is endangering people’s lives has a responsibility to report it.” The NY AG’s settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

E. Although Defendants Knew That Their Marketing Of Opioids Was False And Misleading, They Fraudulently Concealed Their Misconduct.

97. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Cephalon and Purdue entered into settlements in the

1 hundreds of millions of dollars to address similar misconduct that occurred before 2008.
2 Defendants had access to scientific studies, detailed prescription data, and reports of adverse
3 events, including reports of addiction, hospitalization, and deaths – all of which made clear the
4 harms from long-term opioid use and that patients are suffering from addiction, overdoses, and
5 death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based
6 on the medical evidence that conclusively expose the known falsity of Defendants’
7 misrepresentations.

8 98. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid
9 detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and
10 fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing
11 of chronic opioid therapy by funding and working through third parties like Front Groups and
12 KOLs. Defendants purposefully hid behind the assumed credibility of these individuals and
13 organizations and relied on them to vouch for the accuracy and integrity of Defendants’ false and
14 misleading statements about the risks and benefits of long-term opioid use for chronic pain.

15 99. Defendants also never disclosed their role in shaping, editing, and approving the
16 content of information and materials disseminated by these third parties. Defendants exerted
17 considerable influence on these promotional and “educational” materials in emails,
18 correspondence, and meetings with KOLs, Front Groups, and public relations companies that were
19 not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC,
20 did not disclose Endo’s involvement. Other Defendants, such as Purdue and Janssen, ran similar
21 websites that masked their own direct role.

22 100. Finally, Defendants manipulated their promotional materials and the scientific
23 literature to make it appear that these items were accurate, truthful, and supported by objective
24 evidence when they were not. Defendants distorted the meaning or import of studies they cited and
25 offered them as evidence for propositions the studies did not support. The lack of support for
26 Defendants’ deceptive messages was not apparent to medical professionals who relied upon them
27 in making treatment decisions, nor could it have been detected by the People.
28

1 101. Thus, Defendants successfully concealed from the medical community, patients, and
2 health care payers facts sufficient to arouse suspicion of the claims that the People now assert. The
3 People did not know of the existence or scope of Defendants' industry-wide fraud and could not
4 have acquired such knowledge earlier through the exercise of reasonable diligence.

5
6 **F. By Knowingly Causing an Explosion in Opioid Prescribing, Use, Misuse, Abuse, and**
7 **Addiction Through Their Deceptive Marketing Schemes and Unlawful and Unfair**
8 **Business Practices, Each Defendant Has Created or Assisted in the Creation of a**
9 **Public Nuisance.**

- 10
11 1. Defendants' Deceptive Marketing Scheme Has Caused and Continues to Cause a
12 Huge Increase in Opioid Prescriptions and Use in California, Including Santa Clara,
13 Orange and Los Angeles counties and the City of Oakland.

14 102. Defendants' misrepresentations deceived and continue to deceive doctors and
15 patients in California, including Santa Clara, Orange and Los Angeles counties and the City of
16 Oakland, about the risks and benefits of long-term opioid use. California doctors, including doctors
17 in Santa Clara County, confirm this. Studies also reveal that many doctors and patients are not
18 aware of or do not understand these risks and benefits. Indeed, patients often report that they were
19 not warned they might become addicted to opioids prescribed to them. As reported in January
20 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids
21 were potentially addictive. Indeed, California residents in treatment for opioid addiction, including
22 residents of Santa Clara County, confirm that they were never told that they might become addicted
23 to opioids when they started taking them, were told that they could easily stop using opioids, or
24 were told that the opioids they were prescribed were less addictive than other opioids.

25 103. Defendants knew and should have known that their misrepresentations about the
26 risks and benefits of long-term opioid use were false and misleading when they made them.

27 104. Defendants' deceptive marketing scheme and their unlawful and unfair business
28 practices caused and continue to cause doctors in California, including doctors in Santa Clara,
Orange and Los Angeles counties and the City of Oakland, to prescribe opioids for chronic pain
conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive
marketing scheme and their unlawful and unfair business practices, these doctors would not have

1 prescribed as many opioids to as many patients, and there would not have been as many opioids
2 available for misuse and abuse or as much demand for those opioids.

3 105. Defendants' deceptive marketing scheme and their unlawful and unfair business
4 practices also caused and continue to cause patients in California, including patients in Santa Clara,
5 Orange and Los Angeles counties and the City of Oakland, to purchase and use opioids for their
6 chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing
7 scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients
8 using opioids would be using less of them. Again, California doctors and patients confirm this.

9 106. Defendants' deceptive marketing and their unlawful and unfair business practices
10 have caused and continue to cause the prescribing and use of opioids to explode in California,
11 including Santa Clara, Orange and Los Angeles counties, and the City of Oakland. Opioids are the
12 most common means of treatment for chronic pain; 20% of office visits now include the
13 prescription of an opioid, and 4 million Americans per year are prescribed a long-acting opioid.
14 This surge in opioid use was not fueled by any scientific developments demonstrating that opioids
15 were safe and effective for previously unaccepted uses; instead, it was fueled by Defendants' desire
16 to sell more drugs.

17 107. In California, including Santa Clara, Orange and Los Angeles counties, and the City
18 of Oakland, Defendants' deceptive marketing of the abuse-deterrent properties of their opioids
19 during the past few years has been particularly effective. For example, one survey reports that pain
20 specialists were more likely to recognize that OxyContin had abuse deterrent properties and to
21 prescribe OxyContin specifically because of those properties. Further, prescribers who knew of
22 OxyContin's abuse deterrent properties were using more of it than those who did not know it was
23 an AD opioid. Although sales of AD opioids still represent only a small fraction of opioids sold
24 (less than 5% of all opioids sold in 2015), they represent a disproportionate share of opioid sales
25 revenue (\$2.4 billion or approximately 25% in opioid sales revenue in 2015).

26 108. The dramatic increase in opioid prescriptions and use corresponds with the dramatic
27 increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on
28

1 opioid marketing totaled approximately \$91 million in 2000. By 2011, that spending had tripled to
2 \$288 million.

3 2. By Causing an Explosion in Opioid Prescriptions and Use, Defendants Have Created
4 or Assisted in the Creation of a Public Nuisance in California, including Santa Clara,
5 Orange and Los Angeles Counties and the City of Oakland.
6

7 109. The escalating number of opioid prescriptions written by doctors who were
8 deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic
9 increase in opioid addiction, overdose, and death throughout the U.S. and California.

10 110. Representing the NIH's National Institute of Drug Abuse in hearings before the
11 Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that
12 "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity
13 of the current prescription drug abuse problem."

14 111. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to be
15 sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and
16 linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the
17 "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of
18 [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for
19 legitimate pain."

20 112. Scientific evidence demonstrates a strong correlation between opioid prescriptions
21 and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has
22 quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving
23 prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the
24 CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to
25 reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

26 113. Contrary to Defendants' misrepresentations, most opioid addiction begins with
27 legitimately prescribed opioids. In 2011, 71% of people who abused prescription opioids got them
28 through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and

1 substance abuse counselors in California, including in Santa Clara County, note that many of their
2 patients who misuse or abuse opioids started with legitimate prescriptions, confirming the
3 important role that doctors' prescribing habits have played in the opioid epidemic. Treatment
4 centers in California, including centers in Santa Clara County, report that they treat a significant
5 percentage – i.e., as high as 80% – of patients for opioid addiction. For example, one addiction
6 treatment center in Santa Clara County reported that half of their opioid patients started with
7 legitimate prescriptions, and that 75% of those patients later moved to illicit sources or drugs.
8 Another counselor in Santa Clara County reported that almost all of the opioid addicts she treats
9 began with legal prescriptions.

10 114. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. For
11 example, in 2015, opioids were responsible for 286 overdose deaths in Orange County – a 16%
12 increase since 2013 and a 63% increase over figures from a decade ago. In Santa Clara County,
13 which has a little more than half the population of Orange County, prescription opioids were
14 responsible for 134 overdose deaths in 2015 – nearly twice the figure from 2005. In Los Angeles
15 County, opioids were responsible for 344 overdose deaths in 2016 – a 56% increase from 2001. In
16 2016, there were 51 opioid overdose deaths in Alameda County, with the highest burden of deaths
17 appearing to be in Oakland.

18 115. These deaths represent the tip of the iceberg. According to 2009 data, for every
19 overdose death that year, there were nine abuse treatment admissions, 30 emergency department
20 visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-
21 medical users. And as reported in May 2016, in California, opioid overdoses resulting in hospital
22 visits increased by 25% (accounting for population growth) from 2011 to 2014. In Los Angeles
23 County, prescription opioid-related hospitalizations increased 30% from 2006 to 2013 (11,230 to
24 14,594); while prescription opioid-related emergency department visits increased 171% in the same
25 time period (3,354 to 9,075). The number of Los Angeles County medical examiner toxicology
26
27
28

1 cases testing positive for fentanyl doubled from 2015 to 2016.²⁰ Oakland's Fire Department and
2 other paramedics administered Narcan more than 500 times per year from 2015-2017 to help
3 prevent opioid overdoses from resulting in fatalities.

4 116. The overprescribing of opioids for chronic pain caused by Defendants' deceptive
5 marketing scheme has also resulted in a dramatic rise in the number of infants in California who
6 are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence
7 syndrome. These infants face painful withdrawal and may suffer long-term neurologic and
8 cognitive impacts.

9 117. Opioid addiction is now the primary reason that Californians seek substance abuse
10 treatment, and admissions to drug treatment facilities in California more than doubled from 2006-
11 07 to 2010-11. Addiction treatment centers indicate that many of their patients – for one facility in
12 northern California, up to 90% – started on legal opioid prescriptions.

13 118. Defendants' creation, through false and misleading advertising and other unlawful
14 and unfair conduct, of a virtually limitless opioid market has significantly harmed communities in
15 California, including Santa Clara, Orange and Los Angeles counties, and the City of Oakland.
16 Defendants' success in extending the market for opioids to new patients and chronic pain
17 conditions has created an abundance of drugs available for non-medical and criminal use and
18 fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are
19 abused come, directly or indirectly, through doctors' prescriptions.

20 119. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has
21 also resulted in an explosion in heroin use. Almost 80% of those who used heroin in the past year
22 previously abused prescription opioids. And as reported in May 2016, heroin overdose deaths in
23 California spiked by 34% from 2011 to 2013.

24 120. Many patients who become addicted to opioids will lose their jobs. Some will lose
25 their homes and their families. Some will get treatment and fewer will successfully complete it;
26

27 _____
28 ²⁰ Substance Abuse and Prevention Control, Medical Director's Brief (Los Angeles
Department of Public Health).

1 many of those patients will relapse, returning to opioids or some other drug. Of those who continue
2 to take opioids, some will overdose – some fatally, some not. Others will die prematurely from
3 related causes – falling or getting into traffic accidents due to opioid-induced somnolence; dying in
4 their sleep from opioid-induced respiratory depression; suffering assaults while engaging in illicit
5 drug transactions; or dying from opioid-induced heart or neurological disease.

6 121. Absent each Defendants’ deceptive marketing scheme and their unlawful and unfair
7 business practices, the public health crisis caused by opioid misuse, abuse, and addiction in
8 California, including Santa Clara, Orange and Los Angeles counties and the City of Oakland,
9 would have been averted or much less severe.

10 122. The mother of one patient who became addicted to OxyContin and then heroin
11 wrote to the People recounting such a story: “I want [my son] to have the chance at life he had
12 before he became addicted to OxyContin. And really, not just [him]. But every single youth that
13 the doctors and pharmaceutical companies have destroyed just so they could put another dollar in
14 their pockets. Shame on them forever. My son wanted to be a [b]iologist when he grew up. He was
15 a strong boy. He was a good boy. He is not the same boy.”

16 123. These harms in California, including in Santa Clara, Orange and Los Angeles
17 counties, and the City of Oakland, caused by Defendants’ deceptive marketing schemes and
18 unlawful and unfair business practices are a public nuisance because they are “injurious to health”
19 and interfere “with the comfortable enjoyment of life” and “property” (Civ. Code, § 3479) and
20 because they “affect[] at the same time” “entire communit[ies]” and “neighborhoods” and “any
21 considerable number of persons” (*id.*, § 3480).

22 3. Defendants Knew and Should Have Known That Their Deceptive Marketing
23 Schemes Would Create or Assist in the Creation of this Public Nuisance in Santa
24 Clara, Orange and Los Angeles Counties, and the City of Oakland.
25

26 124. Defendants knew and should have known about these harms that their deceptive
27 marketing and unlawful and unfair business practices have caused and continue to cause in
28 California, including in Santa Clara, Orange and Los Angeles counties, and the City of Oakland.

Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors in California, including doctors in Santa Clara, Orange and Los Angeles counties, and the City of Oakland, to prescribe and patients in California, including patients in Santa Clara, Orange and Los Angeles counties and the City of Oakland, to use their opioids for chronic pain.

4. Defendants’ Conduct and Role in Creating or Assisting in the Creation of this Public Nuisance Is Not Excused by the Actions of any Third Parties and Justifies Greater Civil Penalties.

125. Defendants’ actions are not permitted nor excused by the fact that their drug labels may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants’ misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

126. Nor is Defendants’ causal role broken by the involvement of doctors. Defendants’ marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients’ suffering and of practicing medicine more compassionately.

127. Finally, each Defendants’ conduct and role in creating or assisting in the creation of the public health crisis now plaguing California is directly relevant to the amount of the civil penalties to be awarded under Business & Professions Code §§ 17206 [“In assessing the amount of the civil penalty, the court shall consider any one or more of the relevant circumstances presented by any of the parties to the case, including, but not limited to, the following: the nature and seriousness of the misconduct, the number of violations, the persistence of the misconduct, the

length of time over which the misconduct occurred, the willfulness of the defendant's misconduct, and the defendant's assets, liabilities, and net worth," emphasis added] and 17536 [same].

G. Defendants' Fraudulent Marketing Has Led To Record Profits.

128. While the use of opioids has taken an enormous toll on the State of California and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and misleading advertising and other unlawful and unfair conduct described above.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

FALSE ADVERTISING

Violations of Business and Professions Code Section 17500, *et seq.*

(Against all Defendants)

129. The People reallege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

130. Business and Professions Code Section 17500 (Section 17500) makes it unlawful for a business to make, disseminate, or cause to be made or disseminated to the public "any statement, concerning . . . real or personal property . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

131. As alleged above, each Defendant, at all times relevant to this Complaint, violated Section 17500 by making and disseminating false or misleading statements about the use of opioids to treat chronic pain, or by causing false or misleading statements about opioids to be made or disseminated to the public.

132. As alleged above, each Defendant, at all times relevant to this Complaint, violated Section 17500 by making statements to promote the use of opioids to treat chronic pain that omitted or concealed material facts, and by failing to correct prior misrepresentations and omissions, about the risks and benefits of opioids. Each Defendant's omissions, which are false and

1 misleading in their own right, render even their seemingly truthful statements about opioids false
2 and misleading.

3 133. As alleged above, Defendants' statements about the use of opioids to treat chronic
4 pain were not supported by or were contrary to the scientific evidence, as confirmed by recent
5 pronouncements of the CDC and FDA based on that evidence.

6 134. As alleged above, each Defendant's conduct, separately and collectively, was likely
7 to deceive California payors who purchased or covered the purchase of opioids for chronic pain.

8 135. At the time it made or disseminated its false and misleading statements or caused
9 these statements to be made or disseminated, each Defendant knew and should have known that the
10 statements were false or misleading and therefore likely to deceive the public. In addition,
11 Defendants knew and should have known that their false and misleading advertising created a false
12 or misleading impression of the risks and benefits of long-term opioid use and would result in
13 unnecessary and improper opioid prescriptions and use.

14 136. Pursuant to Business and Professions Code Section 17535, the People request an
15 order enjoining Defendants from any further violations of Section 17500, *et seq.*

16 137. Pursuant to Business and Professions Code Section 17536, the People request an
17 order assessing a civil penalty of two thousand five hundred dollars (\$2,500) against Defendants
18 for each violation of Section 17500, *et seq.*

19 **SECOND CAUSE OF ACTION**

20 **UNFAIR COMPETITION**

21 **Violations of Business and Professions Code Section 17200, *et seq.***

22 **(Against all Defendants)**

23 138. The People reallege and incorporate by reference each of the allegations contained
24 in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

25 139. Each Defendant is named in this Cause of Action for its activities that occurred
26 within four years of the filing of this action.

1 140. Business and Professions Code Section 17200 (Section 17200) prohibits any
2 “unlawful, unfair or fraudulent business act or practice[.]” Defendants have engaged in unlawful,
3 unfair, and fraudulent business practices in violation of Section 17200 as set forth above.

4 141. Defendants’ business practices as described in this Complaint are deceptive and
5 violate Section 17200 because the practices are likely to deceive consumers in California.

6 142. Defendants knew and should have known at the time of making or disseminating
7 these statements, or causing these statements to be made or disseminated, that such statements were
8 false and misleading and therefore likely to deceive the public. Defendants’ omissions, which are
9 deceptive and misleading in their own right, render even Defendants’ seemingly truthful statements
10 about opioids false and misleading. All of this conduct, separately and collectively, was likely to
11 deceive California payors who purchased, or covered the purchase of, opioids for chronic pain.

12 143. Defendants’ business practices as describe in this Complaint are unlawful and
13 violate Section 17200. These unlawful practices include, but are not limited to:

- 14 a. Defendants falsely advertised opioids in violation of the Sherman
15 Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE
16 § 110390;
- 17 b. Defendants manufactured, sold, delivered, held, or offered for sale
18 opioids that had been falsely advertised in violation of the Sherman
19 Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE
20 § 110395;
- 21 c. Defendants advertised misbranded opioids in violation of the
22 Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY
23 CODE §§ 110290, 110398, and 111330;
- 24 d. Defendants received in commerce opioids that were falsely
25 advertised or delivered or proffered for delivery opioids that were
26 falsely advertised in violation of the Sherman Food, Drug, and
27 Cosmetic Laws, HEALTH & SAFETY CODE § 110400;
- 28 e. Defendants manufactured, sold, delivered, held, or offered for sale
opioids that had been misbranded in violation of the Sherman
Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE
§§ 110290, 111440, and 111330;
- f. Defendants misbranded opioids in violation of the Sherman Food,
Drug, and Cosmetic Laws, HEALTH & SAFETY CODE
§§ 110290, 111445, 111330;

- g. Defendants received in commerce opioids that were misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 111450, and 111330;
- h. Defendants proffered for delivery opioids that were misbranded in violation of the Sherman Food, Drug, and Cosmetic Laws, HEALTH & SAFETY CODE §§ 110290, 111450, and 111330;
- i. Defendants failed to adopt and comply with a Comprehensive Compliance Program in violation of HEALTH & SAFETY CODE § 119402;
- j. Defendants represented that opioids had sponsorship, approval, characteristics, ingredients, uses, or benefits which they did not have in violation of the Consumer Legal Remedies Act, CIV. CODE § 1770(a)(5);
- k. Defendants represented that opioids were of a particular standard, quality, or grade when they were of another in violation of Consumer Legal Remedies Act, CIV. CODE § 1770(a)(7);
- l. Defendants disparaged the goods of another by false or misleading representation of fact in violation of Consumer Legal Remedies Act, CIV. CODE § 1770(a)(8);
- m. Defendants Purdue and Endo unlawfully failed to identify and report suspicious prescribing to law enforcement and health authorities; and
- n. Defendants made or disseminated, directly or indirectly, untrue, false, or misleading statements about the use of opioids to treat chronic pain, or causing untrue, false, or misleading statements about opioids to be made or disseminated to the general public in violation of Section 17500.
- o. Defendant Purdue directly or indirectly offered or paid remuneration to doctors to prescribe its opioid products in violation of WELFARE & INSTITUTIONS CODE § 14107.2,

144. Defendants' business practices as described in this Complaint are unfair and violate Section 17200 because they offend established public policy, and because the harm they cause to consumers in California greatly outweighs any benefits associated with those practices.

145. As a direct and proximate result of the foregoing acts and practices, Defendants have obtained an unfair advantage over similar businesses that have not engaged in such practices.

146. Each time a Defendant marketed opioids in violation of Section 17200 constitutes a separate violation. BUS. & PROF. CODE § 17206(b). The People therefore seek civil penalties up to

1 \$2,500 per violation pursuant to Section 17206 for each violation of Section 17200. The People
2 also seek civil penalties up to \$2,500 per violation under Section 17206.1.

3 **THIRD CAUSE OF ACTION**

4 **PUBLIC NUISANCE**

5 **Violations of California Civil Code Sections 3479 and 3480**

6 **(Against All Defendants)**

7 147. The People reallege and incorporate by reference each of the allegations contained
8 in the preceding paragraphs of this Complaint as though fully alleged in this Cause of Action.

9 148. Civil Code Section 3479 provides that “[a]nything that is injurious to health ... or is
10 indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere
11 with the comfortable enjoyment of life or property ... is a nuisance.”

12 149. Civil Code Section 3480 defines a “public nuisance” as “one which affects at the
13 same time an entire community or neighborhood, or any considerable number of persons, although
14 the extent of the annoyance or damage inflicted upon individuals may be unequal.”

15 150. Civil Code section 3490 states that “[n]o lapse of time can legalize a public
16 nuisance, amounting to an actual obstruction of public right.”

17 151. Pursuant to Section 731 of the Civil Code, this action is brought by the People to
18 abate the public nuisance created by the Defendants.

19 152. Each Defendant, acting individually and in concert, has created or assisted in the
20 creation of a condition that is injurious to the health and interferes with the comfortable enjoyment
21 of life and property of entire communities or neighborhoods or of any considerable number of
22 persons in Santa Clara, Orange and Los Angeles counties, and the City of Oakland, in violation of
23 Civil Code Sections 3479 and 3480.

24 153. The public nuisance is substantial and unreasonable. Defendants’ actions caused and
25 continue to cause the public health epidemic described above in Santa Clara, Orange and Los
26 Angeles counties, and the City of Oakland, and that harm outweighs any offsetting benefit.

27 154. Defendants knew and should have known that their promotion of opioids was false
28 and misleading and that their deceptive marketing scheme and other unlawful, unfair, and

1 fraudulent actions would create or assist in the creation of the public nuisance – i.e., the opioid
2 epidemic.

3 155. Defendants' actions were, at the very least, a substantial factor in opioids becoming
4 widely available and widely used. Defendants' actions were, at the very least, a substantial factor in
5 deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic
6 pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have
7 become so widespread, and the opioid epidemic that now exists would have been averted or much
8 less severe.

9 156. The public nuisance – i.e., the opioid epidemic – created, perpetuated, and
10 maintained by Defendants can be abated and further recurrence of such harm and inconvenience
11 can be abated.

12 157. Pursuant to Code of Civil Procedure § 731, the People request an order providing
13 for abatement of the public nuisance that Defendants created or assisted in the creation of, and
14 enjoining Defendants from future violations of Civil Code §§ 3479 and 3480.

15 **VI. PRAYER FOR RELIEF**

16 THE PEOPLE pray that the Court:

17 158. Declare that Defendants have made, disseminated as part of a plan or scheme, or
18 aided and abetted the dissemination of false and misleading statements in violation of the False
19 Advertising Law.

20 159. Enjoin Defendants from performing or proposing to perform any further false or
21 misleading statements in violation of the False Advertising Law. Any injunctive relief the People
22 may obtain against Purdue in this action shall not be duplicative of any injunctive terms that remain
23 in place from the Final Judgment.

24 160. Order Defendants to pay civil penalties for each act of false and misleading
25 advertising, pursuant to Business and Professions Code Sections 17500 and 17536.

26 161. Declare that Defendants have engaged in unlawful, unfair, and deceptive business
27 acts and practices in violation of the Unfair Competition Law.
28

1 162. Enjoin Defendants from performing or proposing to perform any acts in violation of
2 the Unfair Competition Law. Any injunctive relief the People may obtain against Purdue in this
3 action shall not be duplicative of any injunctive terms that remain in place from the Final
4 Judgment.

5 163. Order Defendants to pay civil penalties for each act of unfair and unlawful
6 competition, pursuant to Business and Professions Code Section 17206.

7 164. Order Defendants to pay civil penalties for each act of unfair and unlawful
8 competition perpetrated against senior citizens or disabled persons, pursuant to Business and
9 Professions Code Section 17206.1.

10 165. Order Defendants to pay treble the amount of all relief awarded by the Court,
11 pursuant to Civil Code Section 3345.

12 166. Declare that Defendants have created a public nuisance in violation of Civil Code
13 Sections 3479 and 3480.

14 167. Enjoin Defendants from performing any further acts in violation of Civil Code
15 Sections 3479 and 3480.

16 168. Order Defendants to abate the public nuisance that they created in violation of Civil
17 Code Sections 3479 and 3480.

18 169. Order Defendants to pay the cost of the suit.

19 170. Provide such further and additional relief as the Court deems proper.
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1 DATED: June 8, 2018

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PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF ORANGE

I declare that I am over the age of eighteen (18) and not a party to this action. My business address is: ROBINSON CALCAGNIE, INC., 19 Corporate Plaza Drive, Newport Beach, CA 92660. My email address is: dperkins@robinsonfirm.com

On June 8, 2018, served the foregoing document described as:
SIXTH AMENDED COMPLAINT FOR VIOLATIONS OF CALIFORNIA FALSE
ADVERTISING LAW, CALIFORNIA UNFAIR COMPETITION LAW, AND PUBLIC
NUISANCE, SEEKING CIVIL PENALTIES, ABATEMENT, AND INJUNCTIVE RELIEF
on the parties in this action by placing a true copy thereof in a sealed envelope addressed as stated
on the attached mailing list as follows:

 X (By Electronic Service www.onelegal.com) I caused each document to be sent by electronic transmission through One Legal, LLC, through the user interface at www.onelegal.com to all email addresses on the list maintained by One Legal.

 (By Electronic Service) I caused each document to be sent by electronic service by transmitting a true and correct PDF version as indicated above of the foregoing document(s) via each individual's email

 (By Federal Express) Said documents were delivered to an authorized courier or driver authorized by the express service carrier to receive documents with delivery fees paid or provided for.

 (By Mail) I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing. Under practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid at Newport Beach, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

 (By Personal Service) I caused each document to be delivered by hand to the office of the addressee.

 X STATE: I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on June 8, 2018, at Newport Beach, California.

/s/ Darleen Perkins

Darleen Perkins

SERVICE LIST

The People of the State of California, etc., vs. Purdue Pharma L.P., et al.
Orange County Superior Court Case No. 30-2014-00725287-CU-BT-CXC

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